

ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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DALRYMPLE CONFERENCE ROOM
 THE U.S. ARMY MEDICAL RESEARCH
 OF INFECTIOUS DISEASES
 1425 PORTER STREET
 FORT DETRICK
 FREDERICK, MARYLAND

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TUESDAY

MAY 22, 2001

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PRESENT:BOARD MEMBERS:

F. MARC LaFORCE, M.D., President
 LINDA ALEXANDER, Ph.D.
 DAVID ATKINS, M.D.
 S. WILLIAM BERG, M.D.
 PIERCE GARDNER, M.D.
 L. JULIAN HAYWOOD, M.D.
 JOHN HERBOLD, DVM
 PHILIP J. LANDRIGAN, M.D.
 WILLIAM L. MOORE, M.D.
 DENNIS F. SHANAHAN, M.D.
 ROSEMARY SOKAS, M.D.
 KEVIN M. PATRICK, M.D.
 ROBERT E. SHOPE, M.D.
 DOUGLAS CAMPBELL, M.D.

LtCOL. RICK RIDDLE, USAF
 AFEB Executive Secretary

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PRESENT: (CONT.)

PREVENTIVE MEDICINE OFFICERS:

MAJ. BRIAN BALOUGH, USA, MC
COL. DANA BRADSHAW, USAF, MC
LtCOL. MAUREEN FENSOM, CFMS
CDR. SHARON LUDWIG, USPHS
CAPT. K.W. SCHOR, MC, USN
COL. ANDREW S. WARDE, BVETMED
COL. BEN WITHERS, USA, MC
CAPT. ALAN J. YUND, MC, USN

FLAG STAFF OFFICERS:

RADM (Sel) STEVEN HART, MC, USN
MG JOHN S. PARKER, USA, MC

COL. ROBERT DRISCOLL, USAR, MS
JAMES A. ZIMBLE, M.D.

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P-R-O-C-E-E-D-I-N-G-S

(7:20 a.m.)

DR. LaFORCE: If you all will settle in, we are going to start off with some presentations this morning.

LtCOL. RIDDLE: We want to thank Col. Eitzen and the United States Army Medical Research Institute of Infectious Diseases for hosting this meeting of the AFEB, and especially to Col. (Ret) Ted Hussey for coordinating the meeting arrangements.

The first thing this morning, we want to take this opportunity to do some presentations for several members of the Board who have served with the Board over the last four or five years. So, first off, is Dr. Rosemary Sokas.

Dr. Rosemary Sokas, the Assistant Secretary of Defense for Health Affairs awards this Certificate of Appreciation for exceptionally meritorious service as a member of the Armed Forces Epidemiological Board from August 1996 to July 2001. As an AFEB member and member of the Environmental and Occupational Health Subcommittee, your superb leadership, excellent organizational skills, and outstanding professional knowledge produced important policy and program recommendations for the Department's Environmental and Occupational Health Programs.

DR. LaFORCE: Congratulations.

DR. SOKAS: Thank you.

(Applause.)

1 LtCOL. RIDDLE: On behalf of the AFEB and the AFEB
2 staff and members, a plaque and a small token of our appreciation
3 for your service to the Board.

4 DR. SOKAS: Thank you so much, this is beautiful.
5 And I really do want to thank Marc and Ben and Rick and
6 everybody on the Board. It's been an incredibly meaningful
7 experience. And I just do want to say that I think the mission
8 of the Board is so vitally important, and that it's been
9 consistently impressive to me the quality of the preventive
10 medicine that's practiced with in the military and the quality of
11 the Preventive Medicine Officers who offer this incredible
12 service. Thank you all.

13 (Applause.)

14 LtCOL. RIDDLE: Col. Benedict Diniega.

15 DR. LaFORCE: I think you could go anywhere in
16 this world, and somebody would know Ben Diniega.

17 LtCOL. RIDDLE: Col. Benedict Diniega, the
18 Assistant Secretary of Defense for Health Affairs awards this
19 Certificate of Appreciation for exceptionally meritorious service
20 as the Executive Secretary to the Armed Forces Epidemiological
21 Board from August 1998 to November of 2000. Col. Diniega's
22 superb leadership, excellent organizational skills, and
23 outstanding professional knowledge contributed greatly to the
24 Board's ability to produce important policy and program reviews
25 and recommendations for the Department of Defense.

1 On behalf of the Board, the Board staff and
2 members, a plaque for a small token of our appreciation.

3 (Applause.)

4 COL. DINIEGA: I just want to say that it was a
5 good two years. I really enjoyed the Board and the association
6 with the Board goes back to the early days of my career when it
7 was held at Dick Miller's shop every year. Every meeting was
8 there. But I'll still be with the Board, and I know Rick will do
9 a great job.

10 (Applause.)

11 LtCOL. RIDDLE: Col. Ben Withers.

12 Col. Ben Withers, the Assistant Secretary of
13 Defense for Health Affairs awards this Certification of
14 Appreciation for exceptionally meritorious service as the U.S.
15 Army Preventive Medicine Liaison Officer to the Armed Forces
16 Epidemiological Board from July 1999 through July of 2001. Col.
17 Withers' knowledge and willingness to assist and cooperate in all
18 issues brought to the Board contributed greatly to the Board's
19 ability to produce important policy and program reviews and
20 recommendations for the Department of Defense, and a plaque from
21 the Board and the Board staff.

22 (Applause.)

23 LtCOL. RIDDLE: Col. Andrew Warde.

24 I failed to mention that Ben acted as the Interim
25 Executive Secretary when Col. Diniega went over to Health

Affairs, so he had a three-month tour of duty also as the Executive Secretary.

Col. Andrew Warde, the Assistant Secretary of Defense for Health Affairs awards this Certificate of Appreciation for exceptionally meritorious service as the British Army Preventive Medicine Liaison Officer to the Armed Forces Epidemiological Board from May 1997 to July 2001. Col. Warde's contributions significantly broadened the understanding by the Board of Allied military health issues. Here is a plaque from the Board and the Board staff.

DR. LaFORCE: Andrew, before you leave -- Andrew doesn't want anything said, but he's been selected for promotion to General Officer.

(Applause.)

COL. WARDE: I'd like just to say a couple of words -- and I'll make up for it, I promise, by a short Preventive Medicine update. I just want to say that yesterday was a rather gloomy day because I opened an envelope and found in it a ticket for a flight back to the U.K., with no return flight on it because I am afraid I am leaving at the end of July. This has very much cheered me up. My opportunity to work with the Armed Forces Epidemiological Board has undoubtedly been a highlight of the four years of my service here. I shall be extremely sad to leave, and this is the icing on the cake for me, and I really appreciate it. Thank you all very much.

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1 (Applause.)

2 Col. (Ret) Ted Hussey. We can't say enough for
3 all Ted's work in putting this meeting together, and Steve and
4 Teresa and the other folks here on the USAMRIID staff. From Day
5 One, Ted has been knocking the issues out and really helping us
6 putting together an outstanding meeting for the AFEB.

7 Col. (Ret) Ted Hussey, the Assistant Secretary of
8 Defense for Health Affairs awards this Certificate of
9 Appreciation. Col. Hussey's efforts were instrumental in
10 providing for the myriad of support and establishment of a
11 professional working environment aligned for an exceptionally
12 successful and productive meeting of the AFEB.

13 (Applause.)

14 DR. LaFORCE: We will get things started. I did
15 want to formally go through some introductions -- and if members
16 of the Board would just sort of, as I go through, raise your
17 hand, if you will. I don't see Steve Ostroff here.

18 LtCOL. RIDDLE: Tomorrow.

19 DR. LaFORCE: Oh, he's going to come tomorrow.
20 Steve is the Chair of the Subcommittee on Infectious Disease
21 Prevention and Control. Phil Landrigan is here, the Chair of the
22 Subcommittee on Environmental and Occupational Health, and Dave
23 Atkins I rode up with, the Chair of the Subcommittee on Health
24 Maintenance and Promotion.

25 I would ask members of the Board if we could go --

1 I'm just simply going to mention your names again, if you could
2 just signal -- Linda Alexander, whom I saw earlier; Bill Berg;
3 Pierce Gardner I didn't see yet; Julian Haywood; John Herbold;
4 I'm Marc LaForce; Phil Landrigan we already mentioned, Bill
5 Moore, I chatted with him this morning; Steve Ostroff tomorrow;
6 Kevin Patrick; Carol Runyan could not come. She sent me an email
7 yesterday, is actually ill. Dennis Shanahan, Bob Shope, Rosie
8 Sokas we saw, and Doug Campbell.

9 We welcome you all to the Spring 2001 meeting of
10 the Armed Forces Epidemiological Board. The calendar is pretty
11 charged, but I'm going to ask Rick Riddle to go through some
12 administrative announcements before we formally begin.

13 LtCOL. RIDDLE: We certainly want to thank
14 USAMRIID and Col. Eitzen for hosting us. We do have some honored
15 guests that are here, or will be here -- Adm. Zimble, MGEN.
16 Parker will be here this afternoon, RADM. (Sel) Steven Hart is
17 here this morning. Col. Robert Driscoll, also at the head table;
18 Col. Ed Eitzen, the Commander here at USAMRIID; if he's not here,
19 Mr. John Casper, from Army Committee Management; and, for this
20 meeting, Col. Robert Driscoll is the Designated Federal Official
21 for the AFEB.

22 We want to certainly thank Ms. Jean Ward for all
23 the hard work that went into putting one of these meetings
24 together. I had no idea before coming in as Executive Secretary,
25 the effort that goes into bringing our members together, the

1 appointment process, and everything that is involved, and we
2 certainly want to thank Jean for that.

3 Also helping us out this morning is Ms. Lisa
4 Mimms, from ACS. She will be running the Reception area out
5 front, assisting with really any issues that we have, her and Ted
6 Hussey. So, if there's anything that they can help you with or I
7 can help you with, please let me know.

8 Also, for all the Attendees, please sign in at the
9 Registration Desk. And we set the calendar for the next AFEB
10 meeting. Right now, the members' calendars that were turned in
11 looks like 11 and 12 September are open dates for everybody. We
12 haven't got a place, but we will probably have the meeting here
13 in the D.C. area.

14 For today, lunch is on your own. You can either
15 eat at the Community's Activity Center, which is the left as you
16 come in the front gate. I think Ben is going to take some folks
17 over to the NIH Cafeteria. McDonald's and several other places
18 are out the front gate.

19 For tomorrow, it will be a working lunch. Lisa
20 has the menu selections out at the Registration Desk, so if you
21 could go ahead and circle the items on the menu selection and
22 they will bring the lunches in for us tomorrow and we will eat
23 here. It will be \$6.00 apiece, and if you have correct change,
24 they will collect that tomorrow when you pick up your lunch.

25 Restrooms are out to the left, right as you come

1 in the guard area. These two telephones out here in the lobby
2 are local phones -- 2526 and 2566 for DSN and local. For
3 messages for any of the Board members, if somebody needs to get
4 in touch with you here, Teresa's number in the front office is
5 Area Code 301-619-2772 or 2833.

6 For the security clearances tomorrow, the first
7 briefing with Mr. John Birkner is Secret/NOFORN. We do not have
8 clearances for Dr. Atkins, Dr. Herbold, Dr. Campbell, Dr.
9 Landrigan, Dr. Moore, Dr. Shanahan, Dr. Sokas, Dr. Patrick, or
10 Dr. Shope, but it won't matter in the discussion. So, for those
11 individuals, if they will just come late tomorrow, at 8:30, and
12 then we'll bring everybody in after the initial briefing.

13 The discussion, as far as vaccine, is really when
14 you associate the agents with the countries that makes it
15 classified. So, really, just a discussion of the agents, the
16 vaccines, the countermeasures, and the risk assessment, everybody
17 will be able to participate in.

18 We would like to do a photograph of the Board and
19 the PM Officers. If the weather doesn't look good for us this
20 evening, we'll put that off and do it tomorrow.

21 We also have a tour of USAMRIID this afternoon,
22 and so I would like to see a head count on the number of folks
23 that think they want to go on that tour, and we'll meet at the
24 front at around 5:00.

25 For those individuals, what you will have to do

1 is, today, maybe during lunch, at the Guard shack, go ahead and
2 sign in and get an access badge, and we will meet in the lobby at
3 5:00 and we will do the tour, because they just gave us just a
4 meeting room access badge, and for the tour we'll be in and out
5 of the facility. So, if you could do that and, if not, we'll get
6 that done at 5:00.

7 Also, the dinner tonight is at Liberty Road
8 Seafood, and from what I hear it's a very good place to it. It's
9 casual. Maps are in the notebooks and, also, there are some maps
10 on the back table. And to firm up the reservation, could I also
11 get a head count of the number of people that are going to be at
12 the dinner tonight.

13 (Show of hands.)

14 Next reminder is to stay on time, so I'll get out
15 of here. We've had a couple of agenda changes. The BSE
16 information briefs will be first, after the Command brief from
17 Col. Eitzen, so note that on your agenda.

18 And then, lastly, remember that the meeting is
19 being transcribed. If you have a comment or question, please
20 come up to the microphone or speak into the microphone and
21 identify yourself, and also be aware that members of the public
22 and members of the press may be present during the open meeting
23 today, but the meeting tomorrow will be closed.

24 DR. LaFORCE: Col. Eitzen.

25 COL. EITZEN: Good morning, everyone. It's a

1 great pleasure for me and for USAMRIID to have the Armed Forces
2 Epidemiological Board here today and tomorrow. It's a real honor
3 for us.

4 I have a Command Overview of USAMRIID for you. I
5 know that there are several new members of the Board who have not
6 heard this before, when Col. Parker gave it last year, so we'll
7 run through that pretty quickly, and then I'll hopefully have a
8 little time for questions at the end. Next slide, please.

9 (Slide)

10 Well, again, welcome. And if there is anything
11 while you are here during your two days of meetings that I can do
12 to help facilitate and make things run smoother or easier for
13 you, please don't hesitate to ask me or any of my staff. Ted
14 Hussey has done a superb job setting this meeting up and he will
15 be here, but any of us that are here, don't hesitate to ask us
16 for help.

17 Since 1990 the AFEB has met at USAMRIID five
18 times. This is the sixth meeting at USAMRIID since 1990. We are
19 very pleased that the AFEB continues to see USAMRIID as a venue
20 that is a good place to meet.

21 I'd like to personally thank each member of the
22 Board for your service to the Assistant Secretary of Defense for
23 Health Affairs, all the Surgeons General, as well as to our
24 nation and our servicemembers. You do a tremendous service for
25 us to help us through some tough and thorny problems, and we very

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1 much appreciate that. Next slide, please.

2 (Slide)

3 This is USAMRIID's mission. We are here to
4 conduct the research to develop the strategies, products,
5 information, procedures and training for medical defense against
6 biological warfare agents, and also naturally-occurring agents of
7 military importance that require special containment.

8 The first part of that mission is our classic BW
9 defense mission for servicemembers. The second part relates to
10 the containment features of the laboratory and the scientific
11 expertise that's here in the Institute, and so we naturally get
12 asked because of that to get involved in some natural outbreaks
13 as well. Next slide, please.

14 (Slide)

15 Our chain of command is basically from the MEDCOM,
16 the U.S. Army Medical Command. The Surgeon General, LtGen. James
17 Peake, is dual-hatted as the MEDCOM Commander and the Surgeon
18 General. And then down to MGEN. John Parker, my boss, who is the
19 Commander of the U.S. Army Medical Research and Materiel Command.

20 Many of you may not be aware that MRMC, Gen.
21 Parker's command, is a very diverse command of about 5,000
22 individuals, comprising about 12 major subordinate commands to
23 MRMC. We're one of those subordinate commands. So, it's a very
24 diverse and very complex command, probably one of the most
25 complex in the Army Medical Department. And then, of course,

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1 USAMRIID. Next slide, please.

2 (Slide)

3 We have a number of unique capabilities here that
4 allow us to do our mission. We have, of course, the scientific
5 expertise to do the research. We have the ability to do some
6 vaccine testing and drug testing in unusual environments. Not
7 only can we do the basic science, the molecular biology, but we
8 can take the countermeasure, the vaccine or the drug, and test it
9 in animals against the actual live agent. We have the aerosol
10 capability to be able to do that. That's a pretty rare
11 capability in this country.

12 And we also have the ability to do both in-patient
13 and out-patient field trials in clinical studies. We have a very
14 strong diagnostics program which I will speak to a little bit
15 later in the briefing.

16 We have a thing called Operational Medicine, which
17 started in 1991, right after the Gulf War. At the time of the
18 Gulf War, it was recognized here at USAMRIID that we had the
19 scientific expertise, but we didn't have the ability to
20 transition that knowledge very well out to the clinical user in
21 the field, the military Medical Officers that support our Navy,
22 our Air Force and our Army.

23 So, we developed a concept called Operational
24 Medicine here, which was a clinical arm of the Institute, a group
25 of clinicians primarily who are oriented toward transitioning the

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1 knowledge and the products out to the users. And now that small
2 department has grown to a division here of about six physicians -
3 - it changes from year-to-year, the actual number -- and these
4 are people with varied specialties. We have physicians
5 represented in that group from Navy, Air Force and Army, so that
6 we can provide support to all three services. And that, I think,
7 has worked out very well.

8 We have the only maximum BL-4 Containment
9 Laboratory in all of DoD. Next slide, please.

10 (Slide)

11 In terms of scientific expertise, we have about
12 130 to 140 doctorate-level people in the Institute -- Ph.D.s,
13 M.D.s, and Doctors of Veterinary Medicine -- and they make up a
14 group of widely diverse scientific and medical expertise, not all
15 of which is on this slide. This is just a smattering, an example
16 of some of the field that are represented by our people. Next
17 slide, please.

18 (Slide)

19 In terms of our facilities, one of the things that
20 makes us unique is that we have the capability to do studies
21 under BL-3 and BL-4 containment, and we have about 50,000 square
22 feet of Biocontainment Level 3 Laboratory space, and 10,000
23 square feet of BL-4 lab space, the highest level of containment,
24 and that space is really comprised of three separate BL-4 suites.

25 We also have a four-bed Biocontainment Level 4

1 patient care level capability, and this capability can be up to
2 ICU-level care in a contained environment for infectious diseases
3 that would require that level of containment, and we have an
4 aeromedical isolation team that can transport patients to that
5 containment, if that should be necessary.

6 Our clinical research ward is BL-3 capable, and we
7 also have a BL-4 autopsy suite and clinical laboratory. Next
8 slide, please.

9 (Slide)

10 USAMRIID's research basically comes under a
11 program called the Medical Biological Defense Research Program.
12 This program is a DoD-level program that provides about 90
13 percent of the funding that comes into USAMRIID. About 10
14 percent of our funding comes from the Infectious Disease Research
15 Program, the MBDRP, so largely we're funded on biodefense money.

16
17 This makes our life kind of interesting because
18 since the folks up at OSD give us our money and that comes
19 through channels through DTRA down to the Chem/Biodefense
20 Research Program at MPMC and then to USAMRIID, there are people
21 way up in the Pentagon who think that I work for them and, of
22 course, Gen. Parker thinks that I work for him, too, and I know I
23 work for him. So, it makes my life kind of interesting at times,
24 and our life here kind of interesting, because we have this kind
25 of dual situation where our money comes in one way and our

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1 military chain of command is another way.

2 Most of the money is then broken down into three
3 main areas -- toxins, bacteria and viruses. We're kind of
4 stovepiped into agent lines, and the research program is carried
5 out by those three divisions. Next slide, please.

6 (Slide)

7 If you look at some of the products that are used
8 for biological defense, you can see that there are very few that
9 are actually licensed. The two on this slide are the smallpox
10 vaccine Vaccinia, which is an old vaccine that's currently
11 stockpiled by CDC, and then there's also the licensed AVA or
12 Anthrax Vaccine Absorbed, which you are all, I'm sure, very
13 familiar with.

14 We have a number of IND products, investigational
15 new drugs, that have to be given with informed consent. They are
16 used primarily in our laboratory to protect our scientists and
17 technicians when they are working with these agents in the
18 laboratory, and those vaccines are given to them under a program
19 called the Special Immunizations Program here at USAMRIID.

20 And then we have a number of emerging vaccines
21 that we are working on now, really, the next generation of
22 vaccines, which are mostly all recombinant vaccines using cutting
23 edge technology to produce a better, more immunogenic vaccine,
24 with the lowest side effect profile and the lowest number of
25 doses possible. Next slide, please.

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1 (Slide)

2 If you look at the number of vaccines soldiers
3 might have to receive, or sailors or airmen, depending on where
4 they are going in the world, and you look at the range of endemic
5 disease threats as well as BW threats, you can see that our
6 soldiers potentially could end up kind of like pincushions with
7 all the shots they may have to take.

8 One of the things we're trying to do at USAMRIID
9 is to develop some mechanisms to minimize the shot burden to our
10 servicemembers. Next slide, please.

11 (Slide)

12 And two of the ways we're trying to do that are by
13 use of naked DNA vaccines as well as a delivery system called
14 "replicon", and these would provide fewer immunizations, at lower
15 cost, we can custom-design these according to the threats, and
16 hopefully enhance operational readiness. Next slide, please.

17 (Slide)

18 We also are working on a number of treatments,
19 antibiotics and antivirals. And, mainly, since we are not funded
20 at a level where we can start de novo and develop new drugs, what
21 we have to do is take drugs that are in use for other
22 indications, off-the-shelf drugs, and look at them in relation to
23 the threats that are our mission to protect against. Next slide,
24 please.

25 (Slide)

1 We also have a program to look at genetically
2 engineered threats. This started just last year. This was
3 congressional money that came into our program, and basically
4 what we are trying to do here is start to look at common
5 mechanisms of virulence and pathogenicity of these threats, the
6 cascades that they can cause in human beings, to try and
7 interrupt some of those pathways or develop ways to interrupt
8 some of those pathways that might be independent of the agent
9 that's causing the illness. You know, if we ever face a
10 recombinant -- not a recombinant -- but a genetically engineered,
11 possibly recombinant, agent that somebody throws at us, and we
12 are not sure what we are dealing with, we are going to need to
13 have some mechanisms to still protect people or save people in
14 spite of the fact that we may be facing something we've never
15 seen before.

16 This program, again, was funded with about 6
17 million of congressional dollars last year, and that was an add-
18 on to our normal budget. We're hopeful that this will continue
19 so that we can continue to work on these things. Next slide,
20 please.

21 (Slide)

22 I mentioned that we have the ability to do
23 clinical trials here at USAMRIID and in the field. In 1998,
24 USAMRIID conducted a pilot study looking at reducing the vaccine
25 schedule for the anthrax vaccine, as well as changing its route

1 of exposure in terms of how it's given to our servicemembers.
2 And what we did is we looked at reduction of the first three
3 doses from three to two doses, and we also looked at the
4 intramuscular route of administration as opposed to the normal
5 subcutaneous route.

6 What we found in this study was that, number one,
7 there was no change in terms of immunogenicity or antibody
8 levels, or no significant change, by dropping out the two-week
9 dose; and, secondly, that giving the vaccine IM we found still a
10 good immune response, but much lower incidence of local side
11 effects -- you know, red arms and swelling and that sort of
12 thing.

13 So, we took this to the FDA in December of 1998
14 and presented this data to the FDA, and the FDA, as they often
15 do, said, "Well, that's very nice, looks promising. Go back and
16 get us larger numbers".

17 And so the Congress then funded a study in 1999,
18 in the Fall of 1999. The money went to Health and Human Services
19 to CDC, and now CDC is conducting a multi-center pivotal study of
20 about 1500 volunteers to prove that this data really is
21 significant to provide support for a change in the package insert
22 for this vaccine and, again, decrease the number of shots
23 required and hopefully decrease the local side effects. Next
24 slide, please.

25 (Slide)

1 USAMRIID's diagnostic program is a very active
2 research program that's looking at new ways to diagnose these
3 threats. And our Diagnostic Systems Division, under Col. Erik
4 Henschel, as well as collaborators from the Navy and the Air Force
5 work on these new technologies for diagnostics, including ELISA,
6 other immune diagnostics, as well as PCR. And the goal here is
7 to develop miniaturized diagnostic capability that literally can
8 be used at the bedside to diagnose a multitude of these threats,
9 and that's where this defense technology objective is headed, and
10 it's on time and on course, and Col. Henschel is doing a wonderful
11 job as the head of this research program.

12 One of the things that we're able to do because of
13 our relationship with the Theater Area Medical Laboratory, which
14 is the only deployable laboratory in the Army inventory, we're
15 able to test these technologies in a field environment. We have
16 a training site out at the farm, which is another part of Ft.
17 Detrick, across Rosemont Avenue, where the TAML comes here and
18 trains. And we have people in our laboratory, officers and
19 enlisted, who are posted to the TAML and plug into the TAML when
20 the TAML deploys. And so what that gives us is a very robust
21 capability because the expertise goes with the field laboratory
22 when it deploys, and these are people that work on these
23 diagnostics every day of their lives here in our laboratory.
24 Next slide, please.

25 (Slide)

1 This just shows the training site out on our farm,
2 and the joint venture between the 520th TAML, which is a 44th MED
3 Brigade subordinate unit, and USAMRIID, and it's been a wonderful
4 collaboration for us, giving us a way to make sure that what
5 we're doing in the laboratory can be transitioned to the field,
6 used in the field, and is relevant to the wartime environment and
7 supporting the warfighter. Next slide, please.

8 (Slide)

9 I mentioned that USAMRIID supports a lot of
10 endemic disease outbreaks, and this has been historically
11 something that we've done almost every year. Something comes up
12 that we're asked to provide diagnostic help or research support
13 or expertise for. Just in the last two years, we've had the West
14 Nile outbreak in the Northeastern United States that we've been
15 intimately involved in the diagnostic work for that. We
16 supported the CDC with an anthrax outbreak that occurred in
17 Minnesota last fall, and we also have worked to support the CDC's
18 efforts in Uganda with the recent Ebola outbreak there. And we
19 actually -- this bullet here speaks to the fact that we nearly
20 had a U.S. physician, civilian who was working in Gulu, who
21 exposed himself potentially to Ebola in December of this year,
22 and I spent the whole New Year's holiday on the phone with the
23 Pentagon and others from the CDC. We very nearly had this
24 individual evacuated to Ft. Detrick and put in our slammer, our
25 containment suite, for observation and potential treatment, but

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1 he ended going to Europe after all the coordination that
2 occurred. Next slide, please.

3 (Slide)

4 USAMRIID has taken on an increasing role in the
5 interagency response to potential bioterrorism. This has been a
6 mission that has really gained strength over the last five or six
7 years here at the Institute and in many other agencies of our
8 government. Next slide, please.

9 (Slide)

10 We have a number of capabilities that we can bring
11 to bear to support the government in terms of a bioterrorism
12 event. We can provide help in evaluating the threat. Because we
13 work with these agents every day and we have some historical
14 knowledge of their use as weapons in the old offensive program,
15 which stopped in 1970, we have the ability to help with
16 evaluating those threats. We can do the diagnostics. We have
17 the reference laboratory capability for agent confirmation.
18 USAMRIID, in fact, is the reference laboratory for the nation for
19 bacillus anthracis. If the CDC has a question about anthrax,
20 they come to us as the reference laboratory.

21 We have expertise in physical protection, DECON
22 and other areas because, again, we do this every day in the
23 laboratory. We have the medical consultation capability in
24 Operational Medicine Division, and we also are involved in a
25 number of national level CON plans where USAMRIID has a

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1 deployment role in these, including teams like the Foreign
2 Emergency Support Team, the Domestic Emergency Support Team, the
3 Chem/Bio Rapid Response Team, and some of our scientists and
4 physicians will occasionally deploy either on exercises or with
5 real events that may occur. Next slide, please.

6 (Slide)

7 This type of support takes us across a lot of
8 organizational boundaries, and it literally goes from the highest
9 levels of our government all the way to individual military
10 units, depending on the issue. And so it's a very complex
11 environment, but also very rewarding to be able to work with
12 these other agencies.

13 We also work with our Allies on things like this
14 and, in fact, many of our physicians have taught in the
15 biodefense courses of our Allied governments, like the Australian
16 course, the U.K. course, and the Canadian BW defense course.
17 Next slide, please.

18 (Slide)

19 We have a thing called the Special Pathogens
20 Sample Test Laboratory. This is a lab within USAMRIID which is a
21 forensic laboratory that was formally started in 1997 using some
22 funding from both BACTO, the Treaty Organization, as well as
23 DTRA. And this laboratory has the mission of providing
24 analytical support for potential bioterrorism issues. And what
25 happens is, we tend to get samples coming into the laboratory

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1 from the FBI and other agencies, and they want to know what's in
2 it, and we have to handle these in a certain way because they may
3 be used as evidence in a court of law. So there has to be rigid
4 quality control, very good forensics, and a chain of custody
5 involved in managing the analysis of these samples. Next slide,
6 please.

7 (Slide)

8 This slides just gives you an example of some of
9 the events that we're asked to provide diagnostic support to with
10 the Special Pathogens Laboratory. And you can see things like
11 the NATO Summit, the State of the Union Address practically every
12 year now, the Republic and Democratic National Conventions, and
13 occasionally to organizations like the United Nations. Next
14 slide, please.

15 (Slide)

16 I mentioned USAMRIID's Aeromedical Isolation Team.
17 This is a one-of-a-kind capability that allows for evacuation of
18 a highly infectious casualty from anywhere in the world where we
19 can get transportation -- and that's the hooker -- we have to
20 have the Air Force, or somebody, to fly us there and back, but we
21 have these aircraft isolators that enable transport of an adult
22 under BL-4 containment conditions either back to USAMRIID or to
23 another medical center that has containment capability. These
24 teams are two eight-person deployable teams. It's an additional
25 duty for the people that are on these teams, it's not their

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1 primary job, and they train once or twice a month to be able to
2 do this additional mission. Next slide, please.

3 (Slide)

4 USAMRIID has also been very involved in
5 educational work for biodefense and bioterrorism preparedness.
6 We, of course, have our historic in-house course, which now is a
7 combined course between USAMRIID and our sister laboratory, the
8 Medical Research Institute of Chemical Defense down at Aberdeen
9 Proving Ground, and that course is a combined one-week-long
10 chem/bio course, and we put about 120 to 150 students quarterly
11 through that course. We start one group at Aberdeen, one group
12 here at RIID, and then we switch them in the middle of the week
13 so that we can do essentially two courses at the same time. And
14 this is open to mainly military medical officers of all the
15 services. I think it's a very good, clinically-relevant course.
16 Col. Ted Cieslak's division conducts this course, and I think
17 they do a bang-up job on the bio portion, as well as Col. Gary
18 Hurst's division down at ICD also does a phenomenal job with the
19 chemical portion.

20 But even with that number of people, you know, up
21 to 600 people per year put through this in-house course, we
22 realized several years ago that we were just scratching the
23 surface of the educational need. The need just in the military
24 services alone is in the tens of thousands of individuals that
25 need this training.

1 And so we, about four years ago, obtained some
2 money form the Surgeon General's office and started a satellite
3 distance learning program that we've conducted every year in
4 September, Medical Management of Biological Casualties and
5 Bioterrorism, every September since 1997. And in the four years
6 of that program, we've put 52,000-plus health care providers,
7 military and civilian, through that live interactive program,
8 which can be beamed anywhere in the country or overseas via
9 satellite.

10 And the cost of doing that is about 1/20th the
11 cost of bringing a student here to USAMRIID and ICD for the in-
12 house course. And I actually think it's better. We can do a lot
13 of different scenarios in the satellite course. The satellite
14 has won nine different documentary and television awards since
15 its inception in 1997. It would take us about 80 years to
16 educate this number of people in the in-house course, so I think
17 it's been a big benefit.

18 For our success in this program, we are now in a
19 situation this year where we are not getting any funding to do
20 it. There have been additional requirements on OTSG -- you know,
21 real requirements -- that have required them to make some hard
22 decisions about funding. And so we have not been able this year
23 -- although I have been continuing to knock on doors, I haven't
24 been able to come up with funding to do this year's course. So,
25 it's on hold right now. Next slide, please.

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(Slide)

We also have a number of publications out that you are probably very familiar with. You have in front of you the new Fourth Edition of the Blue Book, the Medical Defense Against Biological Warfare Handbook, which has been published since 1992, and I believe that we've probably put that into the hands of well over 100,000 health care providers since we started printing it in the early '90s. It's gone through four different editions.

And our chemical defense colleagues have a very similar handbook that's also gone through several editions. We have the Textbook of Military Medicine, which is kind of the reference book, and our scientists and physicians also publish very widely and broadly in the medical literature. Next slide, please.

(Slide)

USAMRIID works with a number of other agencies on research collaborations, including agencies like DARPA, the NIH, CDC, the DOE Labs, our sister services, the Cooperative Threat Reduction Program involving research in the former Soviet Union, et cetera. And so this, I think, augments our program and makes for a very diverse and collaborative relationship with a number of other agencies. Next slide, please.

(Slide)

These are the "Tech Base" products that USAMRIID brings to bear for the nation, not just the basic research, but

1 also the vaccine candidates, the candidate therapeutics, the
2 testing of those, the diagnostic capability, also the information
3 and the education and the expertise and consultative capability
4 that's always here and available should the country need it.
5 Next slide, please.

6 (Slide)

7 Now, I'd like to share with you -- I've got about,
8 I think, ten more minutes left -- and I'd like to share with you
9 just a few slides that came out of a briefing I gave to the whole
10 Institute about a month ago, in April, called "The State of
11 USAMRIID", and this was basically designed to give our people my
12 sort of overview on where we are, and I thought it might be
13 interesting to the Board members to hear from me where I thought
14 the Institute was in terms of how we are doing right now. You
15 know, you have heard the canned briefing, you know, all the fluff
16 and the good stuff. Let me tell you now kind of where we are.
17 Next slide, please.

18 (Slide)

19 I think we are in excellent shape overall, and the
20 reason I say that is because, first of all, we have committed,
21 very committed, outstanding people all throughout this Institute.
22 We have lots of people who could walk out of here and increase
23 their salaries by 50-100 percent easily, with the state of
24 biotechnology today. But for some reason, which I'm very
25 grateful for but don't quite understand, a lot of these people

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1 elect to stay here. There is something about USAMRIID that makes
2 people want to stay here and work here. It's a spirit that I
3 really can't quantify for you.

4 We have excellent leaders in all the areas of the
5 Institute, both research and operational, and we are now about
6 7600 strong in terms of civilians, military and contractors
7 whereas several years ago, in the mid-'90s, we had about 450
8 people. So we've grown significantly, but that's also created
9 some problems for us in terms of the fact that we are bursting at
10 the seams space-wise, but it's given us a lot more expertise
11 bringing in those additional people.

12 Funding-wise, we are in much better shape than we
13 have been in the past. In the mid-'90s, '96-'97 time frame, the
14 total budget of USAMRIID was in the \$18 to \$25 million a year
15 range. That's barely enough to keep the lights on here and keep
16 the place running. It takes about \$17-18 -- at that time, it
17 took about \$17-18 million just to keep everything going and pay
18 salaries, so we didn't have much money for the research.

19 Now, of course, our overhead has increased, but
20 we're now at a level where we're bringing about \$52 million a
21 year. About \$43 million of that is core research dollars, and
22 the rest of it is reimbursables for the other work we're doing
23 for other agencies that we collaborate with. So, compared to
24 where we were in the mid-'90s, we're in pretty good shape there.

25 Next slide, please.

(Slide)

What about facilities? This building is getting pretty old. It's about 31 years old now, and much of the containment equipment, the infrastructure that allows us to do what we do, is original equipment. But, fortunately, past Commanders and facility managers have done a great job of keeping this place in good shape, and all the containment laboratories were renovated in the mid-'90s, and we have several renovation projects going on as we speak. So, for its age, the facility is in pretty good shape, but we're going to need a new USAMRIID, and we're going to need it in about ten years or less, I believe.

We've started a Master Facilities Plan this year to start the process of MILCON, military construction, to build a new facility.

What about reputation? Well, I think we are better known than ever before, both nationally and internationally, and it's a credit to the work of our scientists and our physicians. It is a tremendous honor for me to be in this position to represent those people because they are the reason USAMRIID is what it is. Without the people, we wouldn't have much of anything. We would have the shell and the infrastructure, the building, but we wouldn't have the ability to do what we do.

And I think overall, at least in the military, we're still the "go to" organization for the nation for

1 biological defense matters. Next slide, please.

2 (Slide)

3 What are my four top priorities for this Institute
4 over the next couple of years? One of the things we really need
5 to do is get some new products out there for our servicemembers.

6 We've got some aging vaccines. We've got some areas where we
7 don't have a countermeasure at all. And so over the next two
8 years, I hope to transition to advanced development three key
9 products -- the new recombinant anthrax vaccine, the FIV Plague
10 vaccine, and the common diagnostic systems that come out of our
11 DST research program.

12 I want to work hard to improve quality of life
13 within the Institute, including our processes to get things done
14 day-to-day better for our scientists. That's very important in
15 recruiting, retention and professional development of our staff.

16 Probably my most important job is, when I leave here, if I can
17 say that we've kept the scientific expertise or even enhanced the
18 scientific expertise of the Institute, we've still got our
19 talent, and that's probably my most important job, and it's going
20 to be an area of emphasis.

21 And, finally, we're going to work very hard with
22 the Joint Vaccine Acquisition Program and the JPO, who are the
23 advanced developers for our products that are transitioned into
24 advanced development, to bring them to licensure. Those
25 organizations don't belong to us, they are DoD-level

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1 organizations, but we're going to work very hard to improve the
2 relation with JVAP and JPO, and we're already working hard on
3 that. Col. Danley and I talk very regularly to make the process
4 work so that advanced development is really kind of integrated
5 into this Institute early on in the life of a product, and we
6 take more of the pharmaceutical industry model to bring these
7 products to licensure better, because our track record, quite
8 frankly, in the biodefense world is not real good.

9 We're probably under-funded for the scope of what
10 we're trying to do, still, but we can do better, I think. Next
11 slide, please.

12 (Slide)

13 Some other areas of focus for me will be to try
14 and bring in some operational funding for the operational
15 components of our mission -- some of the bioterrorism support,
16 some of the things our Operational Medicine Division does, as
17 well as some of the educational programs. As I've alluded to in
18 the briefing, we have some problems with consistent funding in
19 this area, and that's going to be a focus for me to try and fix
20 that during my time in command.

21 And we are right now rebuilding our Clinical
22 Vaccine Studies capability. That was hurt by the loss of several
23 people at one time two summers ago, and we're going to complete
24 the job of revitalizing our Special Immunizations Program to make
25 sure it's completely up to all FDA regulatory standards. We kind

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1 of have right now a mini-Manhattan project going on here with our
2 SIP program, to get data entered and to bring everything up to
3 state-of-the-art FDA regulatory guidelines. That program -- to
4 do this, to make sure that the SIP program is functioning and
5 provide support for our employees is going to cost me \$3- to \$4
6 million a year, to keep these old vaccines up-to-snuff and going
7 for our people. That's not an insignificant cost in our budget.

8 Next slide, please.

9 (Slide)

10 And we're going to work toward building a new
11 USAMRIID eventually, and making better use of the space that we
12 have. We're going to try and increase teaming across divisional
13 boundaries in the Institute, to make for more collaborative and
14 better research here, and to use the talents that we do have in a
15 better way.

16 And the ultimate goal, of course, is to maintain
17 relevancy to where the Army and the DoD are going, including Army
18 transformation and all of the effort to revitalize our Armed
19 Forces. Next slide, please.

20 (Slide)

21 So, that's USAMRIID. USAMRIID, I truly believe in
22 my heart and every day I walk in this building, I kind of pinch
23 myself because I think that we're a unique resource for this
24 nation. We're not just an MPMC or an Army or a DoD resource, we
25 are a national resource because there is just not another place

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1 like USAMRIID in this country. And we're here to create medical
2 products and information for the warfighter, for those who
3 support the warfighter, and for our country.

4 That's my briefing to you this morning. I hope
5 I've stayed on time. And I don't know, Dr. LaForce, if I might
6 have time to take a question or two.

7 DR. LaFORCE: I think we've got time for a few
8 questions. I would start off by asking you, from your
9 perspective, what's your biggest threat? In other words, what is
10 the biggest hazard that USAMRIID faces, or the biggest challenge
11 that it faces over the next two or three years?

12 COL. EITZEN: That's a good question.

13 DR. LaFORCE: I mean, this all sounds terrific,
14 this is wonderful, but what's the other side? In other words,
15 what's the risk side? I mean, is your funding stable? Is the
16 core funding stable? I mean, 40 out of 52 or 55, is that extra
17 \$15 million pretty stable, because it sounds like that's the
18 edge. That's what gives you the flexibility to be able to do the
19 stuff that you're talking about, right?

20 COL. EITZEN: Yes, sir. I have a number of
21 thoughts on your question, so let me kind of give a little flight
22 of ideas here.

23 We are responsible right now, if you look at our
24 STOS and DTOS, our technology objectives, we are responsible for
25 getting out about 15 or 20 different medical products, vaccines

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1 or drugs or diagnostic systems. The level of investment that a
2 big pharmaceutical company would have for that type of a research
3 program would be at least ten or more times the level of funding
4 we are funded at currently. So, although our funding is better
5 than it was in the mid-'90s and it's stable, it's going to
6 increase slowly over the next three or four years, I still
7 strongly believe that we are under-funded for what the DoD is
8 expecting us to accomplish.

9 Now, we have historically here done a lot with a
10 little, so I'm hopeful that we can continue to produce without
11 the levels of funding that you would expect to see in industry
12 for a program that we're trying to accomplish. So, that's one
13 risk.

14 The second area of risk -- I think there is an
15 issue floating out there that I didn't mention in the briefing,
16 which has to do with biosecurity. There are people starting to
17 nose around laboratories like USAMRIID, who are saying, "What are
18 you doing about making sure that Ebola or Lassa Fever or one of
19 your pathogens doesn't walk out of this laboratory?" And the
20 word "biosurety" gets mentioned a lot.

21 And some of the people who are talking about this
22 issue are people who come from a DOE nuclear background -- you
23 know, of barbed wire fences and armed guards and a lot of things
24 like that, in an environment where you can count things every day
25 to make sure something is not missing.

1 And some of the people that we're trying to talk
2 to about this issue or are trying to engage really don't
3 understand the work we do. The CDC has this problem. We have
4 this problem. The folks at Plumb Island have this problem. I'm
5 afraid that if we don't come to some reasonable measures -- and
6 this will affect university laboratories, by the way, too,
7 because there's a lot of extramural stuff going on -- so that's a
8 major issue for us, I think, that's coming in the next couple of
9 years, that we're going to have to grapple with.

10 And, you know, our safety record is pretty good,
11 but if something were to happen unusual -- you know, we had an
12 explosion or somebody, you know, an insider were to do something
13 unusual -- that could be, I think, a great risk to the
14 laboratory.

15 Overall, I think things are going well, as I said,
16 but we do face some risks and some issues.

17 DR. LaFORCE: Other questions for Col. Eitzen?
18 Yes?

19 DR. BERG: Bill Berg, Hampton Health Department.
20 I have a comment and a question. I hope, regarding the
21 biosurety, you can get the word out how this -- you know, your
22 safety record, how this does differ from Department of Energy
23 concerns.

24 What went through my mind when you started
25 mentioning this was what happened about eight to ten years ago

1 regarding NIOSH and tuberculosis, in which NIOSH wanted to bring
2 its expertise dealing with industrial hygiene and mining and the
3 need for respiratory protection to a hospital environment, which
4 was totally inappropriate, and in a worst-case scenario, you were
5 trying to take care of people dressed in almost a BL-4
6 containment suit. So, I hope you can be proactive and get the
7 word out.

8 The question I had is that the Board, over several
9 meetings, has urged development of a Staph Enterotoxin B vaccine,
10 and you didn't mention that in your briefing. Where do you stand
11 on that?

12 COL. EITZEN: We're in good shape on that. We've
13 had a pre-IND meeting with the FDA. We've got a formal package
14 that we've presented to them, and we've got an IPT that is in
15 process to bring that product on to advanced development, so
16 we're in pretty good shape there. That one -- you know, I don't
17 see that -- you didn't see that on my top four priorities, but it
18 is a priority. It's just not quite up there with those other
19 three.

20 DR. BERG: Thank you.

21 COL. EITZEN: And that's based on the landscape
22 that I see out there. The people that we work for are really
23 demanding the next generation anthrax vaccine, they are demanding
24 a plague vaccine, and they are demanding the diagnostics, and the
25 other reason those three are at the top of the list is because

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1 they are the closest, that we have the best chance of getting
2 them out in the very near future, although SEB is right there
3 with them. It shouldn't take us very long to get SEB into
4 advanced development either.

5 DR. LaFORCE: We should move on. Thank you, Col.
6 Eitzen. Look forward to the tour this afternoon.

7 An administrative announcement. Anyone who has
8 got a Nissan Sentra, Mississippi license plate 1428B, your lights
9 are on. Thank you.

10 We're going to begin the Preventive Medicine
11 updates, and Col. Diniega will begin. Col. Diniega is the
12 Program Director for Preventive Medicine and Surveillance, the
13 Office of the Assistant Secretary of Defense for Health Affairs.

14 Ben?

15 COL. DINIEGA: Good morning, and thanks again,
16 Marc. The updates are very interesting because whoever makes the
17 schedule gets beat up because there are nine people trying to
18 talk within 70 minutes, so we always try to give some time to the
19 people we know will take a longer time to give their updates.

20 I just want to mention a few items to the Board as
21 an update or a new issue but, first, I want to mention that the
22 Joint Preventive Medicine Policy group works on a lot of the
23 Preventive Medicine issues at their monthly meetings, and they
24 really get a lot of work and issues resolved at the multi-service
25 level.

1 (Slide)

2 The first item is the continuing saga of shortage
3 of vaccines, and those vaccines that are at-risk are always
4 discussed at every meeting with the Joint Preventive Medicine
5 Policy group.

6 The Tetanus Toxoid issue, the shortage is still
7 there, and it's expected to continue to early 2002 at the best.
8 We are experiencing in all the services, difficulty in obtaining
9 adequate vaccine to do recruit vaccinations and some of the
10 large-scale, routine preparation for overseas movement exercises.

11 The group, as a whole, agreed at the last meeting
12 to put the message out at the service levels to remind people
13 that recruit vaccinations and routine 10-year booster are in
14 lower categories. There are six categories recommended for
15 prioritization by the ACIP, and we have put recruit vaccinations
16 and routine 10-year deployments in the lowest category.

17 Deployers to high-risk diphtheria countries are
18 still very at the top of the list.

19 (Slide)

20 Influenza: There had to be a DoD policy
21 memorandum last year because of the shortage, and there are
22 categories for prioritization of immunization put out at the DoD
23 level. Usually, the influenza programs are handled at the
24 service levels.

25 This year, the vaccine was changed. One of the

1 components was changed. The manufacturers do not expect problems
2 with any production, and so at this point no shortage is expected
3 for the vaccine, however, the vaccine cost will rise
4 significantly. And as far as the implementation of routine
5 vaccination is down to age 55. CDC has not made a decision on
6 whether or not that should be implemented this year or not. It
7 would require an additional, they estimate, about 15 million
8 doses for the nation if they were to lower the age this year, but
9 they should be making that decision sometime this summer. The
10 next meeting of the ACIP is in June.

11 (Slide)

12 And the last item on my list is near and dear to
13 the Board in this meeting of the Board. Two years, in 1998, the
14 Board made significant recommendations on the BW Threat List and
15 what other things should be looked at besides vaccines, and I
16 just want to let the Board know that there's been progress made,
17 and you will hear about it tomorrow when we talk about the
18 Medical Risk Assessment project that the Army, as executive
19 agent, has worked on.

20 But we have begun discussions with the people who
21 generate the Threat List, DIA, and also the proponent of the DoD
22 directive that mandates the use of the BW Threat List and vaccine
23 development, and the proponent for that directive is the
24 Secretary of Defense for Threat Reduction and
25 Counterproliferation. So, we are engaged in ongoing discussions

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1 on looking at how the directive needs to be changed. And,
2 certainly, the AFEB discussions over these next two days, and
3 especially tomorrow, will impact greatly on what the final
4 outcome of those discussions about the DoD directive and the
5 Threat List will look like. And that's all I have. Any
6 questions?

7 DR. LaFORCE: Except I would make the observation
8 that I really am chagrined to hear the story about Tetanus
9 Toxoid. When I looked this up several years ago, as I recall,
10 all the casualties during the Second World War led to a sum
11 total, I believe, of five cases of tetanus in U.S. Military
12 Forces during the entire Second World War, again, as testimony to
13 the efficacy of this particular antigen and, to me, it is just
14 astonishing that we sort of find ourselves not only here, but
15 also in the civilian sector, everybody is scrambling around
16 looking for really a fundamentally important agent in terms of
17 the general immune protection of the American population, not
18 only the warfighter but everybody.

19 COL. DINIEGA: You're very right. The impact of
20 shortages of vaccines goes through all of the sector -- public,
21 military and private sector. There are many groups working on
22 this. The Interagency Vaccine Group discusses this on a regular
23 basis at their weekly, or their monthly teleconferences, and the
24 U.S. Medicine Institute had a vaccine forum recently, co-
25 sponsored between DoD and Military Medicine. And the IOM is also

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1 taking a look, and the National Vaccine Program Office is taking
2 a look, at the recurring shortages that have occurred in our
3 country.

4 DR. LaFORCE: Thank you, Ben. I'm sorry,
5 questions?

6 RADM(Sel) HART: The question I was going to ask
7 was pretty much what Dr. LaForce asked. Specifically, since the
8 impact of this sort of protection is most greatly felt on
9 readiness in the warfighter, so our population has a greater
10 interest than anybody else, what is our -- how do we monitor
11 industry so that we anticipate -- instead of investigate why
12 there is a shortage, how we anticipate that there is a change in
13 capacity, or a potential change in supply?

14 COL. DINIEGA: We, at the military level, at least
15 at the Preventive Medicine level, we have discussed this at our
16 meetings, and we are linking up more with the Logistics
17 Acquisitions people now, and we've asked them to monitor the
18 industry. I think some of the things that have happened are all
19 driven by business practices, many of them -- you know, is it
20 profitable and, as people merge, they get rid of the less
21 profitable arenas. And vaccines are very expensive to produce
22 now, and there are less companies interested. And the CDC also
23 is taking a look at ways to get more people involved in vaccine
24 production.

25 I think it requires a national strategy, but I can

1 tell you, the Preventive Medicine Working Group is acutely aware
2 of the problem, and we are trying to make the links to monitor
3 what's happening -- with our Logistics colleagues, to monitor
4 what's happening in the vaccine production arena. And they
5 provide us quarterly updates on the pharmaceutical activities
6 that would impact on our supplies.

7 DR. LaFORCE: Thank you. Next speaker is Col.
8 Withers, the Preventive Medicine Staff Officer, the Office of the
9 Army Surgeon General.

10 COL. WITHERS: Good morning, everybody. President
11 LaForce and distinguished members of the Board, I am Col. Ben
12 Withers, Army Representative.

13 (Slide)

14 This will be my agenda for this morning. I'll
15 pick up where Col. Diniega left off on the tetanus shortage.
16 First, let's just enjoy a few pictures.

17 (Slide)

18 So, that is, of course, Kopialani Park and
19 Waikiki, and we all stayed there.

20 (Slide)

21 This is, of course, taken from Diamond Head. This
22 is a beautiful shot of the Diamond Head Lighthouse, which you
23 only get if you are on Diamond Head. You can barely see it as
24 you drive by it, it is literally behind a home, but what a lovely
25 picture that was.

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1 (Slide)

2 And this is Ben on Lanakai Beach. The islands
3 behind are called the Mokoluas, Big and Little Mokolua. They are
4 about 2200 meters off the shore. And I swam out to them on two
5 occasions. They are both wildlife sanctuaries, and people go out
6 there to just hang out and party. And on the back side of Big
7 Mokolua, which is to the left, there's a famous jumping place.
8 It's about a 30-foot cliff, and people go there -- it's kind of
9 dangerous -- but people go back there and you hike around and you
10 jump off there several times. So, I've done that in the past.

11 (Slide)

12 Okay, let's get back to work for a second. We, in
13 the Army, went ahead and initiated a policy memorandum on the 2nd
14 of January to help our field deal with the tetanus shortage, but
15 at the time the tetanus shortage looked like it would be a mild
16 and short-lasting thing.

17 So, as the situation worsened, we decided we
18 needed to give -- to really dig in for the long haul and to give
19 very detailed guidance to the field. As you may realize, people
20 in the field always want details.

21 So, on 3 May, the JPMPG did establish a statement
22 on prioritization, and I took that and drafted up an Army Policy
23 which is currently in the works. As I've told you many times,
24 nothing happens quickly, but I'm hopeful of having a new Army
25 policy out within two weeks.

1 (Slide)

2 Now, to give you an idea of what the JPMPG, or
3 Joint Preventive Medicine Policy Group, did, we took the CDC
4 priorities -- and there they are, paraphrased -- and we simply
5 took all the military groups that people would ask questions
6 about and put them somewhere in the six CDC priorities, and
7 that's what you're seeing in yellow. Basically, in white is just
8 what CDC said, and we, the JPMPG, augmented it with the yellow
9 writing. Any questions on that?

10 (No response.)

11 Okay. Having none, we will move back to Hawaii.

12 (Slide)

13 This is most of the Service Preventive Medicine
14 Officers and their frau right by the -- this is after we got off
15 the board ride.

16 (Slide)

17 Okay. Moving on to the next topic, I told you
18 last time that our varicella policy was in final staffing. It
19 still is, unfortunately. The reason is, as you know, we have
20 five training posts whereas the other services have one,
21 excepting the Marine Corps which has two, and that does
22 complicate matters. It's just harder to get consensus, and
23 anytime you do anything you've got to do it five times, and
24 there's a lot more overhead for doing anything. Chlamydia
25 screening is another good example of why it took us a little

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1 longer to implement that at the IET level -- why it will take us
2 longer to implement at the initial entry training level.

3 But, anyway, Ft. Jackson has both the highest
4 numbers of trainees in the Army, and also we have a fairly
5 impressive range of incidence, and Ft. Jackson enjoys the lowest
6 incidence of varicella.

7 So, they came back with a nonconcurrence and,
8 again, you've always got to try to build consensus before you
9 give these things to the Surgeon General, so we went ahead and
10 built a new cost-effectiveness model, and I'm just going to
11 present a few of the slides from that.

12 (Slide)

13 First, notice the range. Our range in the Army
14 goes from .93, that's varicella cases per thousand trainees per
15 year, and that again is at Ft. Jackson, all the way up to almost
16 3 cases per thousand per year at Knox.

17 (Slide)

18 I really just want you to look at the yellow
19 writing for a while. These are our costs to the Army Medical
20 Department of what we call the VSVP, that's our new proposed
21 program. So, look at Jackson where we run 38,000 trainees a year
22 through. Based on our screening methodology, which the Board
23 suggested and which we are doing, which is a combination of
24 history and serology to cut our numbers down, to cut our numbers
25 of serology down, so we figure that many titers and that much

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1 vaccine at a cost of that. So, notice that's a large part of the
2 AMEDD total.

3 (Slide)

4 Again, this is costs and savings. Again, the Army
5 Medical Department will cost -- it will cost us \$107,000 per year
6 at Jackson. We'll save \$14,000 in averted hospitalizations. And
7 our Training Command will gain \$54,000 in productivity. But
8 notice, of all the training posts, when you add it all up, Ft.
9 Jackson still comes out at a loss and, again, it's because of the
10 high numbers/low incidence.

11 (Slide)

12 Now, take a moment and soak this in. This is
13 where I sort of compare doing nothing to what we want to do,
14 which is our screening program. The total cost to DA is, in our
15 mind, approximately \$340,000, and I should say this, this
16 estimate is limited only to the eight weeks of initial entry
17 training. I am not, at this point, counting benefit beyond that,
18 which there is, of course.

19 But just looking at the immediate, we're basically
20 just transferring. The total costs come down from \$342K to
21 \$252K, but all we're doing is really transferring costs from
22 TRADOC, \$270K, to the Army Medical Department, \$252K. So there
23 is a savings of roughly \$100,000, we think, during the IET
24 period, but it's not impressive, and it doesn't save us any
25 money. It's an unfunded requirement of the Army Medical

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1 Department. Doesn't mean it's not a good idea, but it really is
2 another unfunded requirement which Health Affairs handed us, and
3 I frankly don't know what the Surgeon General is going to do with
4 it. I won't be surprised if he asks me not to implement until
5 we, you know, go for money, and that won't be until FY '03. I
6 just don't know. I mean, I'm just sort of talking from the hip
7 here. He may -- what we have proposed to him is to say, "Let's
8 just suck it up from everybody's hide", but that presents
9 \$107,000 problem at one MEDEC.

10 (Slide)

11 I took this picture from my hotel room. I was
12 sitting there on my balcony one afternoon, and I saw the sun
13 coming down and the ship coming across, and I thought, I bet you
14 they are going to collide in the middle, and it was just perfect.

15 But, anyway, I show you this to say goodbye. This will be my
16 last meeting as your representative, as the Army Representative,
17 and I do want to say that I've enjoyed my time here. It's been a
18 wonderful opportunity for me, and I want to thank the members of
19 the Board, as Col. Eitzen did, for your service. It does impress
20 me how busy and hardworking you all are and how you graciously
21 give of your time, you make no money on this, and all of your
22 accomplishments are such that you don't really need this service
23 to get your strokes. You are doing a selfless service to our
24 nation, and I really appreciate it. Thank you so much.

25 DR. LaFORCE: Ben, before you go away, the

1 varicella calculations are fine, but you leave out the number of
2 cases that occur over the next two years.

3 COL. WITHERS: Well, I left it out of --

4 DR. LaFORCE: Is that a small number or big
5 number? We looked at that, didn't we?

6 COL. WITHERS: I left it out of what I showed you,
7 but in the report I gave to the Surgeon General I did include
8 that. We estimate that it will take approximately -- if we
9 implement this program today, it will take about six years to
10 achieve about 90 percent effectiveness. In other words, in the
11 whole Army, we figure we will avert about 90 percent of our
12 varicella cases, that will take about 20 percent per year to get
13 there, though. And we estimate a savings to the Army Medical
14 Department of about \$100,000 a year, starting in five years.

15 DR. LaFORCE: That's after you include the
16 prevention of those cases throughout the entire time that someone
17 is in the service.

18 COL. WITHERS: Yes, sir, that's right.

19 DR. LaFORCE: Okay, fine. Questions?

20 CDR. LUDWIG: Do you know what period of time,
21 what years were used to do the incidence calculation?

22 COL. WITHERS: As I recall, it's the last five
23 years.

24 CDR. LUDWIG: The reason I ask is because
25 varicella is cyclical, and I think if you went back farther,

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1 there were higher incidence rates at all --

2 COL. WITHERS: Over a decreasing period of
3 incidence, that's correct.

4 CDR. LUDWIG: -- it might have made a difference
5 to Ft. Jackson to see that.

6 COL. WITHERS: Another thing to say is that we'll
7 only need this program for maybe 10 or 12 -- you know, some
8 decreasing -- starting in 10 or 12 years, we can ramp it down and
9 do something different. But the other thing to add is that this
10 is what we want to do now. Starting in two to three years, we
11 want to do full serology and do MMRV -- do a serologic battery,
12 do MMRV, and then selectively vaccinate those that need it.

13 DR. LaFORCE: Okay. Thank you, Ben.

14 Col. Bradshaw, Chief, Preventive Medicine Office
15 of the Air Force Surgeon General. Dana?

16 COL. BRADSHAW: Good morning. I'm just going to
17 be speaking right here from the podium this morning, but I did
18 have a couple of things I wanted to talk to you about. One
19 mainly that I want to concentrate on, which I think is actually
20 an issues that is common to all the services now, and that is the
21 issue that's recently been brought up about thimerosal in
22 vaccines for active duty members and dependents, adult
23 dependents, not just the children.

24 I did want to mention, though, that recently in
25 the Air Force we have had a meeting at the Recruit Health

1 Symposium which is down at Lackland this year, and have put
2 together kind of a working group or committee for oversight for
3 our recruit training folks. We felt for a while that we kind of
4 needed to bolster some of the guidance surveillance, and even
5 research in our recruit contingents and training programs, and so
6 Dr. Don Thompson is now at the Air Force Academy, one of our PM
7 DOCs, and he along with the folks that are going to be at AETC
8 and the folks that are at Lackland are going to be working
9 together along with us at the Air Staff, in trying to improve
10 some of the things that we're doing with our recruit populations,
11 modeling some on what our colleagues have been doing in the other
12 services.

13 The issue about thimerosal I wanted to bring up
14 occurred just a few months ago when I was notified that Gen.
15 Ryan, our Chief of Staff, was going to be getting a briefing from
16 an individual who it turns out is a staffer with Senator McCain,
17 and he was also coming up with Chad Hennings, who is a former
18 Dallas Cowboys lineman, and happened to be a personal friend of
19 the Chief of Staff, and they had gained an audience with Gen.
20 Ryan to discuss an issue with him about thimerosal and mercury in
21 vaccines. And it was also somehow linked to Gulf War illness.

22 So, I had to help prepare our Surgeon General and
23 the Chief of Staff to discuss this issue. And it turns out when
24 it was presented that the individual who was presenting actually
25 had been having problems with what he perceived as unexplained

1 Gulf War illness, including symptoms of chronic fatigue, other
2 issues. and during this time, someone had put the bug in his
3 ear, so to speak, that mercury might be the cause of all his
4 problems. And he happened to have his short record back from his
5 military service, and started adding up all the shorts that he
6 had received in preparation to go to deploy, and this included
7 several injections of IGG, tetanus, meningococcal vaccine,
8 influenza, so on, so forth. And that once he added all these up,
9 that he had over 100 micrograms of thimerosal and mercury,
10 thimerosal being about 49 percent mercury by weight.

11 It turns out that he found an individual DO down
12 in Arizona who does collation therapy. Went down, had all his
13 amalgams taken out, had collation therapy, and seemed to have
14 resolution of all his symptoms. So he now was on a campaign to
15 remove thimerosal from all vaccines in the military. Of course,
16 a lot of this, as you probably are aware and recall, is that back
17 in the summer a little while back, the FDA did some calculations
18 and found out that over a six-month period that certain children,
19 especially that were low-birth weight or females, say, in the 5th
20 percentile by weight, would have received as much as 187
21 micrograms of mercury over a six-month period. And it turns out
22 that that amount would be greater than the EPA standard
23 calculated as .1 micrograms per kilogram per day over that entire
24 six-month period.

25 Now, that is the most conservative of the four

standards that are out there. There's the EPA standard, which is the most conservative, and then there's the FDA standard, which is about maybe an order of magnitude larger, the ATSDR standard, and the WHO standard, all of which none of those were exceeded. But as you may recall, that is when the AAP and the CDC and FDA came out with a statement that recommended that we defer hepatitis-B immunization for children at birth, and that the vaccine manufacturers hopefully would remove thimerosal from vaccines at least for children.

Now, if you calculate out what an individual received, most of our vaccines, the ones primarily that contain it that are used commonly right now, are meningococcal vaccine, tetanus vaccine, the influenza vaccines, and a few others, but those are primarily the ones we have. And most of those, a half cc of vaccine contains 25 micrograms of mercury.

In these sort of situations, if you calculate what the EPA standard would be for an individual, a 70-kilogram man could receive 17 micrograms of mercury per day. So, any one day, one shot would be too much if you used the EPA referent dose. The problems is that the EPA referent dose is a dose that's calculated for a lifetime, and the EPA specifically says in the report to Congress on mercury toxicity, that that referent dose is not to be used for bolus or intermittent dosing. They also note in that report that the primary exposure for most of us to mercury in the environment is through eating fish, and for an

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1 example, by comparison, if you eat one can of tuna fish, about 4
2 to 6 ounces, that's about 17 micrograms of mercury, or about what
3 you would get in JEV vaccine, for instance. And over a week's
4 time, the FDA calculates you can have over 200 micrograms of
5 mercury or thimerosal. But, again, this is a situation where
6 people are misunderstanding what the referent dose is, how the
7 EPA calculated it, the base of a lot of their calculations on
8 what would happen to the most sensitive population -- that is, an
9 unborn fetus -- in situations where they've had environmental
10 exposures, particularly in a rock that had seed grain that was
11 treated with a fungicide that contained mercury, was not intended
12 to be eaten, but people baked it into bread, and they had a large
13 number of cases of people having mercury toxicity. And EPA used
14 those standards, took the 5th percentile of that for the most
15 sensitive population, and then took an order of magnitude less
16 than that to make the referent dose calculations.

17 So, it turns out again that Congressman Burton,
18 who many of you probably know from some of the anthrax wars, got
19 hold of this, and one of his issues has been for a long time
20 autism in one of his grandchildren, and so these groups have kind
21 of been communicating. He's had some congressional hearings
22 where he's brought CDC before them. And so they made this
23 presentation. We tried to put things in perspective, but Gen.
24 Ryan has asked us, at least in the Air Force, to see if we can
25 space out our vaccinations.

1 Also, I think the same group has gone and has
2 briefed Adm. Clinton on the same issue, and we are going to be
3 discussing this some more with the Joint Preventive Medicine
4 Policy Group.

5 I've talked to Aventis-Pasteur and Merck and some
6 of the other vaccine manufacturers, and they are moving to try
7 and reduce thimerosal even in adult vaccines. I know, for
8 instance, the Fluzon that Aventis-Pasteur makes is their version
9 of flu vaccine. They are removing to reduce the amount of
10 thimerosal that's in that vaccine. Some of the other
11 manufacturers have already gotten thimerosal out of the
12 hepatitis-B vaccines. And the problem is mainly in our multi-
13 dose vials because thimerosal is in there as a preservative to
14 allow you to use multi-dose vials and not worry about
15 contamination as much.

16 I say this just to at least kind of make you aware
17 that there is kind of a movement out there and some people that
18 are very interested in it that are using a little bit of
19 misunderstanding about how toxicology is done, but that are
20 moving to try and pressure the DoD to get thimerosal out of
21 vaccines, reduce the amount of mercury exposure that we're
22 having. And they link this kind of peripherally to reports and
23 an association with the heavy metals, with ALS. There's a very
24 prominent case of a pilot who flew in the Gulf War, who is
25 currently dying of ALS, and they have concerns about things like

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1 this. And the VA, in fact, is doing a study on Gulf War veterans
2 with ALS, and are going to be measuring mercury exposure, blood
3 and hair samples. Any questions? I just wanted to kind of throw
4 that issue out there.

5 DR. LANDRIGAN: In our hospital in New York City,
6 we have what's called a Pediatric Environmental Health Specialty
7 Unit. It's a clinical unit that's supported by ATSDR that sees
8 children who are thought to have suffered environmental
9 exposures. We've just had a flurry of calls over the last year
10 about vaccines and about mercury, ranging from concerned parents
11 who have never seen an epidemic and think that the vaccination is
12 worse than the disease, to people such as the person you describe
13 who has been advised to have all their fillings pulled. There's
14 really quite a range of attitude out there.

15 That said, there was, as you know, a very
16 authoritative report that came out last summer from the National
17 Academy of Sciences that looked specifically at the situation of
18 prenatal exposure of the fetus to organic mercury in moms who had
19 eaten fish, and they reviewed the three big studies that are out
20 there, the Seychelles Study which found no effect, the study in
21 the Faro Islands which did find an effect, and the study in New
22 Zealand which found an effect, and they came to the conclusion
23 that two is greater than one and that the quality of the two
24 positive studies was better than that of the one negative study,
25 and that therefore organic mercury ought to be considered a fetal

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1 toxin. So, I think that the move which is afoot on the part of
2 the manufacturers to get the thimerosal out of at least the
3 pediatric vaccines is probably a good one.

4 Let me leave you, though, with a brain teaser,
5 something that we haven't addressed yet, and that has to do with
6 the fact that the Rh vaccine which is given three or four times
7 in the course of pregnancy to pregnant moms who are at-risk of A-
8 B incompatibility, contains the thimerosal. So far as I know,
9 there's no plan yet to remove the thimerosal from that vaccine.
10 Given that that organic mercury of course is going to go straight
11 across the placenta into the baby, that might ought to be the
12 next target of opportunity.

13 DR. LaFORCE: Interesting point. Those of us who
14 followed this -- where is Dick Miller -- some of the hype that
15 has surrounded this really sort of goes beyond the bounds of
16 absurdity, and it presupposes that there's absolutely no
17 clearance --

18 DR. LANDRIGAN: There's a thriving industry out
19 there, yeah, that's part of the trouble.

20 DR. LaFORCE: -- and it's really sort of crazy
21 because it's starting to dictate policy in terms of real
22 preventive services. And if you talk to the large vaccine
23 manufacturers, they are in the process of eliminating thimerosal
24 as part of their corporate strategies in terms of improving their
25 vaccines, and many of us, myself included, felt that this was

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1 something that was best left being taken care of on its own, and
2 that I'm not sure much good has come out of all of this.
3 Certainly, a lot of time has been devoted to something that I
4 think could have been devoted a lot more appropriately elsewhere.

5 But it's going to be here for a while.

6 DR. LANDRIGAN: I think it speaks to a larger
7 issue. I mean, I realize that there are various threads of
8 thought that converge on this anti-vaccine movement, I don't want
9 to be simplistic about it, but I think part of it is sort of a
10 challenge to us in the professions to do a better job to educate
11 the public about the value of vaccine. I mean, we have a whole
12 generation of young parents now out there, who have never seen a
13 polio epidemic. I remember when I was a kid in Boston, every
14 August, every September, people headed for the hills because of
15 the threat of polio. No young parent today has ever experienced
16 that in this country, likewise measles, likewise Rubella. And in
17 the absence of any visual picture of the power of those
18 epidemics, people rail against the vaccines.

19 I think maybe there is need for the sort of
20 educational effort that we undertook a few years ago when there
21 was a strong and credible threat against the use of animals in
22 experimentation, and we had to mobilize the NIH, the CDC, the
23 medical community generally, to persuade the public that animal
24 testing was a valid endeavor. Same for vaccines.

25 DR. LaFORCE: Okay. Let's move on. Capt. Yund,

1 the Deputy Director of Preventive Medicine and Occupational
2 Health, Navy Bureau of Medicine and Surgery. Jeff.

3 CAPT. YUND: Thank you, Dr. LaForce. I'm going to
4 try to move fast.

5 (Slide)

6 One brief note about adenovirus vaccine, the
7 Request for Proposals went to the industry in March, and we
8 should have some proposals back in early June. The Source
9 Selection Board will look at those proposals but, again, as
10 everybody is aware, if things go well, it will be a couple of
11 years at least until we have the vaccine back onboard.

12 (Slide)

13 I won't say much about this because it's been
14 covered adequately, I think.

15 (Slide)

16 Meningitis vaccine shortage, worldwide shortage,
17 probably won't affect the U.S. military because it's different
18 vaccines. We use, of course, exclusively, the FDA approved
19 vaccines, and other vaccines produced elsewhere that are mainly
20 in shortage.

21 (Slide)

22 Influenza vaccine has already been touched. We
23 hope we won't experience the production delays this year but, as
24 was already noted before, the price will be higher.

25 (Slide)

1 Just one quick note about Prevnar, our
2 pneumococcal conjugate vaccine heptavalent, it's pretty
3 expensive. DoD has not received the advances in medical progress
4 funding from Health Affairs because the whole Defense Health
5 Program is looking at some red numbers this year. So this is
6 adding a little bit of stress to our medical treatment
7 facilities, and we hope that this is resolved a little bit later
8 in the year, depending on how the congressional plus-up and the
9 size of the congressional plus-up comes along.

10 (Slide)

11 Anthrax really no change at this point. We're
12 going to run out of vaccine probably before the new vaccine or
13 more vaccine is available.

14 (Slide)

15 The Joint Preventive Medicine Policy Group is
16 working on a Joint Service Instruction on deployment health
17 surveillance and protection. We hope that will be pretty close
18 to final product in the next month or two.

19 (Slide)

20 I know many of you have heard about the
21 incinerator at Atsugi in Japan, and I just wanted to make sure
22 that everybody had heard the good news that the government of
23 Japan bought the incinerator and closed it down. Maybe not the
24 end of the story because we have had quite a few people who have
25 been there for a number of years who may or may not have been

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1 exposed to certain bad things, so not totally the end of the
2 story, but at least a very good turn of events in that story.

3 (Slide)

4 Another story that there is really no good news to
5 report, the leukemia cluster in Fallon, Nevada has been reported
6 in a number of national media. Basically, there have been 14
7 cases of leukemia diagnosed since January 1997. This is a fairly
8 small community, 26,000 people, and this is a very tight leukemia
9 cluster with rates probably 30 to 50 times the rate in the
10 population, the U.S. population. Mostly ALL, but one of the
11 recent cases was AML; age up to 19-years-of-age. Three cases now
12 in Navy families. There is a lot of attention focused on this
13 cluster. The Nevada Health Department is working very hard
14 investigating and trying to find a solution, although those of
15 you who are familiar with leukemia clusters know that solutions
16 don't usually come out of the investigations.

17 ATSDR was invited by the Health Department and is
18 beginning their look at Fallon and at NAS, and as far as Navy
19 involvement, of course, the Naval Air Station and Strike Air
20 Warfare Center at Fallon have been extremely involved with the
21 community action team. As far as medical involvement, our
22 Environmental and Preventive Medicine Unit in San Diego, the Navy
23 Environmental Health Center, and the Navy Health Research Center
24 have all been very involved in one way or another, assisting the
25 local community deal with this problem.

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(Slide)

A quick note about our TB Control Program. We put out guidance to update our program and, of course, we are going, as the CDC recommends, to nine months of INH as the primary regimen. We're not doing everything that the CDC guidelines do recommend. The CDC guidelines really recommend that people who have no identifiable risk factor for tuberculosis or acquiring tuberculosis not be screened, and we are not comfortable with that in the Navy and the Marine Corps, so we are going to continue with the three-year testing interval for all personnel, not just personnel who have an identifiable risk factor. A number of our personnel, as you are aware, live in tight quarters on ships for a long period of time, and we want to be absolutely certain that we catch as many cases of active -- prevent and detect as many cases of active tuberculosis as possible.

(Slide)

Finally, I want to tell you just a little bit about the realignment that happened in MED-02. MED-02 is the Assistant Chief for Operational Medicine and Fleet Support. RADM(Sel) Hart right here.

The old situation was that there were -- I say 7 on the slide here, but probably more like 10 or 12 different subcodes, and many different military units in other parts of the country.

The new arrangement is that all of these old

1 entities still exist, but they have been realigned under 3
2 Service Lines which are more or less functionally determined.
3 And we think that the result, the ultimate result which we're
4 starting to see is that the flow of information both directions
5 is improved and streamlined, and people have better access to the
6 different services that are available.

7 (Slide)

8 Just one final slide here, this is the diagram of
9 the whole organization with the three service lines. One,
10 Readiness and Training; another, Preventive Health Programs; and
11 the third is Research and Development.

12 This little corner right here is where my office
13 is, in MED-24. So this is an improvement, we think, in the way
14 the business of MED-02 occurs.

15 (Slide)

16 And that little, tiny word there says "Questions"
17 because we're short of time and I'll move on to the next speaker,
18 unless there is a burning question.

19 DR. LaFORCE: Other than commenting, those Board
20 members who remember the presentation on Atsugi, that was a
21 couple of years ago. This is really wonderful news in terms of
22 that being purchased and demolished, and now it's going to be the
23 vexing issue of following up everybody who was there for a while.

24 But, congratulations. I think that's just splendid news. Yes?

25 DR. SOKAS: And the other comment is just in

1 follow-up of some of the TB presentations that I think the policy
2 is absolutely consistent with the higher risk for --

3 DR. LaFORCE: Capt. Schor, U.S. Marine Corps.

4 CAPT. SCHOR: Good morning. At the risk of
5 stirring interservice rivalry, I want to thank Col. Ben Withers
6 for concluding with that picture of the ship. He failed to
7 mentioned, as he did at the JPMPG meeting, that that is an
8 amphibious assault ship, so he truly understands where the pointy
9 end of the spear is, and lest I have any comments that it is
10 sailing off into the sunset, because it is an anachronism, how do
11 you know it's the sunset, it could be the sunrise. So, thank
12 you, Ben, for providing the entre to the pointy end of the spear
13 there.

14 With that, I will divert from the main theme of
15 this whole meeting and not talk about vaccines or infectious
16 disease. I want to bring a follow-up to half of my presentation
17 in Hawaii and talk about injury prevention.

18 (Slide)

19 At the last meeting, I mentioned that Cdr. Fred
20 Landro, a GPM resident, was doing descriptive epidemiology on a
21 PEB database, a personnel database, that is run by our Manpower
22 shop. He has reported out on his results of his MPH study and
23 found marked differences in rates of attrition by gender, pay
24 grade, occupational specialty, and that's in a 12-month slice,
25 basically April of '99 to April of 2000. And subsequent to the

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1 last meeting of the Board, he has spent about six weeks with me
2 and we put together a plan of action for carrying this on
3 further.

4 (Slide)

5 This is coming up next month. This is the current
6 opening slide to a briefing that he and I will give to the
7 Executive Safety Board. That is a collection of approximately 20
8 to 25 stars. In other words, those are 3-star generals and
9 above. It is chaired by the Assistant Commandant of the Marine
10 Corps. It will be held in Memphis next month, and actually, I
11 think, hosted by Federal Express, interestingly, because they
12 have provided some safety consultation to the Safety Department
13 in the Marine Corps. So, we get to brief them. I think we are
14 the last briefers on the final day, which is not unusual for
15 medical to be the north end of a southbound train, but we're
16 comfortable there, and we're happy to be briefing.

17 (Slide)

18 This is part of what we're going to brief. Fred
19 Landro will brief the data of his analysis to give them an idea
20 of what he has found out, and some of those marked differences in
21 rates. We're looking at these basic issues in the Plan of
22 Action, looking at databases. He's been able to knit together
23 databases. Looking at partnering. Looking at how to sustain
24 this process, and then how to influence policy.

25 (Slide)

1 In terms of databases, the bottom line is we want
2 where the money goes. You know, if you're going to pay somebody
3 to kick them out of the Marine Corps, somebody is going to have a
4 real good database on that because the Marine is going to want
5 you to have a good database on that, and their parents, and their
6 congressman, and everybody else.

7 So, instead of trying to create a new system, we
8 just followed where the money goes, where the Manpower folks do
9 the database, and his entire analysis is based on personnel
10 records, not on medical records. And we found that, you know,
11 it's pretty doggone good, and you can calculate rates off of
12 that, and it gives you good descriptions, and it may provide a
13 good basis for surveillance and trending. We just have to kind
14 of buff-up a few things.

15 We've gone to the Naval Council of Personnel
16 Boards who weigh-in on these cases and decide yea or nay, thumbs
17 up or thumbs down. We're finding that they have a lot of paper
18 records. They have some electronic records. We're actually
19 photocopying some of the paper of Medical Boards for further
20 analysis before they get shipped off someplace in Suitland,
21 Maryland, and we've also made some contacts with the Naval
22 Medical Information Management Center at Bethesda. They have
23 ICD-9 coding. They have the inpatient data record and outpatient
24 data record similar to some of the other databases that we have
25 access to, and they may be able to provide some economic impact

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1 analysis. That remains yet to be determined.

2 (Slide)

3 In terms of partnering, I want to thank, in his
4 absence, though, Dr. Ostroff. He was a key player in providing
5 senior level entre to the National Center for Injury Prevention
6 and Control. Although Dr. Bruce Jones, Colonel, Army Medical
7 Corps (Retired), is a key employee of that Center, and would be
8 very interested in helping any way. The top-down entre that Dr.
9 Ostroff has provided is critical for the great support that we
10 have already gotten and look to get in the future.

11 Fred Landro will be spending three two-week
12 rotations with them, to take a suitcase full of data and provide
13 further analysis. We just had that 12-month snapshot of data.
14 We don't know how stable that is. We want to make sure that some
15 of the marked differences in rates are, in fact, true and not
16 unique to that 12 months of data.

17 We want to ask their expertise to see if we have
18 validated the high-risk target groups to go to further analysis,
19 and they have offered to provide consultation on any future
20 studies with our groups. There's a wealth of data that we can
21 get our hands around.

22 We have approached the Navy Environmental Health
23 Center -- and I mislabeled it as "Naval", I apologize. Adm(Sel)
24 Hart, my mistake. But we looked to them for providing program
25 policy recommendations as this analysis goes further. At this

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1 point, they may provide some data analysis, but that remains to
2 be determined at this point, and NMIMC, as I mentioned
3 previously.

4 (Slide)

5 In terms of taking this existing database and
6 turning it into surveillance and prevention capability, we think
7 it's pretty close to being there. It's not real-time, it may be
8 two or three months delayed, at worst, but in this area, that can
9 provide some reasonable trend analysis over time, to see where
10 injury trends are moving.

11 We think that there may be some very small tweaks
12 in data fields. We found a strategic Marine Corps corporal who
13 can change those data fields, at our request, or Safety
14 Division's request. And we think that some very small changes
15 can bring about an even more robust database that we can build
16 on.

17 We look to getting the support of the Generals at
18 the meeting next month. We think in about a year, after we do
19 some more analysis and validate our target menu in military-
20 speak, that we can energize some Tiger Teams. Let's say the
21 Military Police have a fairly high rate, we'd like to get a Tiger
22 Team going on Military Police folks and other folks that are
23 experts in training and say, why is that? Can you help us figure
24 out why you have these injuries, why you have this attrition, and
25 how we can seek to prevent that. We look at most of these fixes,

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1 obviously, as being engineering fixes and not medical fixes.

2 We're also looking in a whole host of other areas
3 at formalizing how the Marine Corps supports other injury
4 prevention efforts. The Marine Corps has been very interested,
5 especially at the accession pathway level, of supporting things
6 like sports medicine and reconstitution therapy clinics at the
7 MCRD accession points. They have had marked effects on
8 preventing attrition in the Marine Corps so that we don't have to
9 recruit quite as heavily and we can meet all the recruiting
10 targets that have been set forth by the Commandant.

11 There has been a lot of effort at the basic school
12 where officers come into the Marine Corps, at putting a training
13 room in their barracks that existed for six years, so that they
14 go to the training room when they are broken or hurt, rather than
15 going to Sick Call. So it gets them out of the Sick Call model.

16 Marines don't like to be sick, they like to be recognized as
17 athletes that they are, and they all understand the training room
18 because many of them had been college athletes, and that is very
19 appealing to them. But we are trying to get some way of
20 institutionalizing this across the Marine Corps, and I think we
21 are just on the edge of making that happen.

22 And through nonmedical funding, there's the Semper
23 Fit program that deals with everything from STD prevention to
24 alcohol abuse prevention and counseling, and also readiness and
25 fitness. And down at Camp Swampy, Camp Lejeune, I'm assured that

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1 there's great funding for them because there's not a whole lot of
2 local resources down there, and they have Ph.D. level athletic
3 trainers and certified athletic trainers, and they are working on
4 a Return to Readiness, which takes Marines that are in their
5 initial combat training just before they go to their units, and
6 when the orthopedic specialist and the physical therapist have
7 discharged them, the general consensus is that they are only
8 about 70 percent really ready, back up to 100 percent. And they
9 have to discharge them maybe a little bit early because they have
10 to keep the throughput going. There's resource constraints.
11 Return to Readiness steps in and says, "We'll take you from 70
12 percent to 100 percent full reconditioning to where you should be
13 to return to the Marine Corps", to full active duty, and do your
14 thing in a combat scenario.

15 So, we are trying to develop a continuum across
16 nonmedical funding lines and the hospital, to make sure that is a
17 smooth handoff. So, it's kind of a neat approach to things.

18 (Slide)

19 And, finally, just to emphasize, as I'll brief the
20 Executive Safety Board next month, the Commandant's Safety
21 Campaign provides us the entre from a medical and safety
22 standpoint, to effect policy, and as we bring data to the table
23 and try to augment solid decisionmaking, this is what we're
24 hanging our hat on to effect change in the Marine Corps. And
25 with that, that's my brief.

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1 DR. LaFORCE: Questions for Capt. Schor? Yes?

2 DR. PATRICK: Ken, on programs like the Return to
3 Readiness project, do you have the opportunity to do randomized
4 trials to actually see whether or not these work, and develop
5 that level of evidence?

6 CAPT. SCHOR: Right now, we're just trying to
7 prove impact, which is a big struggle to get the data to say
8 what's the baseline before and where are we now. So, we're not
9 anywhere near that point, but we'd sure like to get there. We
10 just don't have the infrastructure to support that. We'd like to
11 get any research partners that would be interested. As the
12 sports medicine Doc down at Quantico says, "You know, ethically,
13 you wouldn't necessarily be able to pay people to go and bring
14 their bodies in and put them through the kind of training
15 punishment that the Marine Corps is happy to provide and they are
16 happy to go through and become Marines". And what a great
17 laboratory to prove some of the intervention concepts. So, we
18 think that that may be an avenue to, in a zero-sum game of
19 personnel and funding, to get some outside resources to use the
20 Marine Corps as it does its mission and executes its training
21 priorities to look at those issues, but we're not there yet, no.

22 DR. SOKAS: I just want to remind you of one of
23 the best stories I think we ever heard in the AFEB, which was
24 down in Parris Island, where they described the problem with
25 stress fractures among female recruits, where there was a lot of

1 turnover. It actually was one of the leading causes of scrubbing
2 out female -- well, not the leading -- it was a significant cause
3 of scrubbing out female recruits, and they figured out that
4 traditionally Armies have marched with their tall people up
5 front. They flipped it so that the short people went up front
6 and they solved the problem, and it was a very impressive story
7 with, you know, kind of your classic surveillance intervention
8 and results model.

9 CAPT. SCHOR: It's amazing. We just had a
10 discussion yesterday how to get this more institutionalized, and
11 it's very clear that things like the SMART Clinics and the effort
12 -- the training room at TBS, have shown incredible retention and
13 decreased attrition and decreased injury, and significant
14 elements of Marine Corps leadership absolutely believe in it.

15 It's still somewhat tied to personalities. It's
16 not a consistent program across the Marine Corps. And,
17 unfortunately, the huge impacts that Navy Medicine and Military
18 Medicine face with huge multi-billion-dollar funding shortfalls
19 and zero-sum games across the services in staffing and issues
20 like that, we had to find more creative ways. And we're finding
21 that if we train Corpsmen and maybe provide Bachelor's and
22 Master's level certification as athletic trainers, that the
23 universities will provide staffing free in the certified athletic
24 trainers, little things like that, and perhaps partnerships for
25 research, you know, with the injury burdens that we see in the

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1 accession pathway and the opportunities for research that that
2 provides. So, we're trying to find those creative solutions.

3 DR. LaFORCE: Thank you, Capt. Schor. Maj. Brian
4 Balough.

5 MAJ. BALOUGH: You threw me for a loop there, sir.
6 Col. Riddle told me I wasn't going to talk. Anyway, I'll just
7 mention a few things --

8 DR. LaFORCE: You can sit down.

9 (Laughter.)

10 MAJ. BALOUGH: I'll take two minutes. A could of
11 things that we're working on, and I'll just throw these out real
12 quick. The immunizations of other than U.S. Forces policy, I've
13 briefed you on that the first time I was here. We are finally at
14 the point, we've got all the CINC plans, the memo is going to the
15 DJF probably today, and that plan -- all the documentation will
16 go up to OSD, so that will be closed out.

17 We are updating our December '98 Joint Staff
18 Deployment Health Surveillance Memo, and a lot of the JPMPG
19 representatives are working on that, and the big difference on
20 that is we are including the environmental surveillance piece.

21 And the last thing I want to mention is, recently
22 we co-sponsored with Col. Schnelle, out of OTSG, the Joint
23 Medical MBC Readiness Conference, and several individuals in here
24 attended that. Adm(Sel) Hart attended as one of our VIPs at the
25 end of the week to receive those briefs.

1 The conference was not a death by PowerPoint, it
2 was a working group conference. A lot of very good work was
3 done. The issues were -- we looked at the anthrax IND protocol,
4 reviewing that; Medical MBC training requirements, installation
5 response to a WMD event, planning rates for MBC casualties,
6 restriction of movement, and BW surveillance. This has been
7 briefed to Gen. Bester and Adm. Mayo, and then we also got to go
8 in and brief LtGen. McDuffy, all very positive. Next week is the
9 CINC Surgeons Conference. They will be briefed on the outcomes
10 of this.

11 Also, next month we are supposed to have a
12 transition team meetings with each of the issue leads, so all of
13 these issues we basically -- I think we jump-started them, got
14 the ball rolling, and we're going to continue working those
15 throughout the next year. And we're also going to try to do
16 similar type of conference next year, maybe some of the same
17 topics, but it will be same type of format. That's all I have.
18 Thank you.

19 DR. LaFORCE: Thank you. Cdr. Ludwig, Preventive
20 Medicine, Epidemiology, U.S. Coast Guard Headquarters.

21 CDR. LUDWIG: Good morning. I'm Cdr. Ludwig, as
22 you said, the Consultant to Adm. Joyce Johnson, the Director of
23 Coast Guard Health and Safety.

24 I'm pleased to announce that as the PM Officer, I
25 am back in my Preventive Medicine position. I was five months

1 away, actually. I sat down and counted it up, it was a long time
2 but, anyway, as OER time comes by, I realize that five months of
3 my year is going to be judged on issues that I am not really that
4 familiar with.

5 In any case, it's not unlikely that you will see
6 Cdr. Mark Tedesco up here again, as he is the only other person
7 in our office with some Preventive Medicine background, and he is
8 the Chief of Medical Readiness. I would also like to say, for
9 interest, that Mark Tedesco is right now in China where he is
10 adopting a beautiful little girl, and will be back probably in
11 about a week and a half.

12 For the Coast Guard, our small size is both an
13 advantage and a disadvantage. In the case of the tetanus vaccine
14 shortage, it hasn't hit us yet. TRACEN Cape May still has plenty
15 of vaccine, but in planning for an eventual shortage, which I
16 believe will hit us, we are looking to cut back the vaccination
17 of the basic training recruits.

18 What we're going to do is try to get them to bring
19 -- we're going to make a greater effort to have them bring their
20 shot records to basic training with them, and actually look at
21 their shot records and, say, if they've had a TD update in the
22 last ten years -- actually, we're going to cut it back to eight
23 years -- but if they've had one in the last eight years, they
24 will not get another one at basic training.

25 One thing to keep in mind about Coast Guard basic

1 trainees is that a majority of them leave basic training and go
2 directly into operational units which have deployments every day.

3 Their deployments include real-life operations with various
4 degree of risk of injury and contact with people from other
5 cultures and other nations.

6 So, what we're going to try to do is save a little
7 bit of what we've got for later, and hope that the shortage
8 doesn't hit us quite as severely.

9 The next subject that I want to talk about -- by
10 the way, I don't have death by PowerPoint, thanks for the segue,
11 Maj. Balough -- tuberculosis has not ceased to be a problem for
12 us. We have, right now -- yesterday I got a report of a fifth
13 conversion, an aircrew member at the Air Station in Sitka,
14 Alaska. I've been talking to a Medical Officer there who is on
15 top of things, and has been discussing with one of the State
16 Epidemiologists, who I also talked to. Interestingly enough,
17 although you immediately think of Alaskan Natives as having a
18 high prevalence of active TB, in Sitka it's actually a lower
19 prevalence than in Mainland U.S.A. So, it's a little bit of a
20 puzzle how these five people have -- by the way, these five
21 people have converted in the year 2001, so fairly small amount of
22 time.

23 The immediate thought is what's the methodology
24 and who is interpreting the tests and so on. From my
25 discussions, it sounds like it's fairly reliable. So, depending

1 on how things go through the chain of command and so on, I may be
2 going to do an outbreak investigation. If you will remember, I
3 did one a year ago in Florida, which turned out to be an
4 overzealous interpretation of TB tests. I would like it very
5 much if that's what we found here, but I have a suspicion it may
6 be a little more serious.

7 That all being said, one of the things I've gotten
8 going during the time that I wasn't really in my job is some
9 surveillance, some TB surveillance. I had a unit at the Marine
10 Safety Office in Philadelphia that felt certain that their risk
11 of conversion or exposure to tuberculosis was higher than what I
12 had estimated in our new policy of less frequent testing.
13 Initially, they had developed a plan where they were going to
14 test every six months, and I made it pretty clear that that was
15 not appropriate, but they insisted that they would really like to
16 test every year. So, what I did was take that as an opportunity
17 to find out if we can what the risk is in this Marine Safety
18 Office Unit that is willing to do the testing on a yearly basis,
19 and that's probably going to start very soon. The letter went
20 out yesterday.

21 And if possible, we may try to extend that to
22 other Marine Safety Offices. These are people who go aboard
23 ships that are usually crewed by people from countries that have
24 a high risk of tuberculosis. We felt that probably people with
25 active TB are not probably crewing a ship because they need to be

1 pretty good, strong, able-bodied persons, but we will see what we
2 can find out. And I discussed this with the folks at the CDC, and
3 they recommended that that's what we do also.

4 The last thing I wanted to touch on is acute
5 respiratory disease or febrile respiratory illness rates at Cape
6 May peaked -- well, I don't know if it peaked, I hope it peaked -
7 - last week at just under the epidemic threshold of 1.5 per 100
8 per week. I hope it's a peak, but we kind of doubt it as you are
9 shaking your head. We seem to have a lot of adenovirus at Cape
10 May. Since we started the surveillance program, I think we've
11 seen among the different sites that are being monitored at the
12 Navy Health Research Center that Cape May is one of those that
13 has peaked a number of times above the threshold. So, we are in
14 a position to ask for expedited processing of the specimens that
15 we send to NHRC should this occur.

16 We did have a small problem with some specimens
17 that were sent there recently, that were thawed by the time they
18 got there. I'm hoping that we have solved that problem. They
19 were having some problems getting some dry ice. I think that's
20 solved.

21 That's my presentation for this morning. If there
22 are any questions, or do we have time for questions?

23 DR. LaFORCE: Questions from Board members?

24 (No response.)

25 Col. Warde, British Medical Liaison Officer, Army

1 Surgeon General.

2 COL. WARDE: Ladies and gentlemen, I've just got
3 two main things to update you on. The first is an update on the
4 U.K. Surgeon General's policy on vaccination. Until recently,
5 there have been efforts to reduce the number of vaccinations
6 routinely administered to all service personnel. For example,
7 typhoid and hepatitis-A vaccines were given only when personnel
8 were to be deployed to an area where there was a significant risk
9 of infection. But following the rapid deployment to Sierra
10 Leone, Medical Services in the U.K. were criticized for the fact
11 that not all those personnel who deployed had received the
12 appropriate preventive measures. You probably remember the
13 report I provided the last AFEB meeting on the malaria cases in
14 Sierra Leone.

15 The main changes then that are being introduced
16 now are a reintroduction of routine typhoid vaccination, the
17 introduction of hepatitis-A vaccination, and the introduction of
18 routine low-dose diphtheria vaccination given in combination with
19 tetanus vaccine which, by the way, I'm told is not in short
20 supply in the U.K.

21 So, the policy on that sort of timeless military
22 medical dilemma of whether to implement preventive measures "just
23 in case" or "just in time" has swung back now really to the just-
24 in-case end of the spectrum as a result of the increasing demands
25 of readiness.

1 There are other policy developments of the U.K.
2 Surgeon General -- for example, prevention of malaria, the
3 management of HIV and AIDS, smoking cessation and injury
4 prevention -- and these are all being currently prepared, and I
5 will brief my successor to report on these to the Board at future
6 meetings.

7 My final point relates to anthrax vaccination. A
8 few weeks ago, Ministers announced the imminent resumption of the
9 U.K. voluntary anthrax vaccination program, and I understand that
10 this week the instructions will be issued by the Chief of Defense
11 staff. The supply of vaccine in the U.K., of anthrax vaccine in
12 the U.K., is now reliable enough to resume the program for
13 specialist BW defense troops and for all personnel deployed to
14 the Gulf Region on operations. And that's a total at any one
15 time of about 2,500 personnel, and I have no doubt that the
16 resumption of this program will also be the subject of reports to
17 the Board in the future. That's all I have, sir.

18 DR. LaFORCE: The anthrax vaccine is produced at
19 Porten?

20 COL. WARDE: It is produced by the Center for
21 Applied Microbiological Research, which is actually physically
22 located very close to Porten. It's a Department of Health
23 institution.

24 DR. LaFORCE: And that's a fully approved vaccine?

25 COL. WARDE: Yes, this is a vaccine -- it's not

1 exactly the same as the U.S. vaccine, but it is of similar
2 antiquity. It's been licensed for many years, and the cessation
3 of the U.K. program, though it parallels with the U.S. problems
4 of supply, it was the production program that produced the
5 problems. But now production has resumed and implementation has
6 been announced.

7 DR. LaFORCE: Thank you. We will finish this
8 morning's session with Lt. Col. Fensom, Assistant Defense Attache
9 for Health Affairs in the Canadian Embassy.

10 LtCOL. FENSOM: Good morning. I'm new to this
11 job, having taken over from my predecessor, Frank Suiter, and I'd
12 like to begin by bringing you all his best wishes and greetings.

13 He'd like you all to know he's enjoying life as a civilian and
14 very active on the JVAP work on the Canadian side.

15 I have just a few short points for you. One,
16 information regarding our restructure in the Canadian Forces
17 Medical Service. As you may or may not know, we are in the midst
18 of a massive reorganization, which is good for me because they
19 are so busy with that in Ottawa they don't bother me too much
20 down here, but part of that involves firming in a complete
21 medical command of resources which, as you can imagine, is quite
22 massive, especially for the operators to digest, but as of 1
23 April, all our medical personnel, right down to all the Role-1
24 medics are under command of our Director of General Health
25 Services.

1 The relevant point for this group, I think, is
2 that the real winners in the reorganization have been our
3 Directorate of Health Promotion and Preventive Medicine, which
4 will see a doubling of its size over the next year, and that's
5 very exciting for us, and I expect it's going to give us,
6 although small numbers, quite a large increase in capability.

7 We are also looking at some major policy changes,
8 particularly in the area of HIV, and I've managed to put our POC
9 up in Ottawa in contact with yours down here at OASD through Col.
10 Powers, so I'll be doing the same in terms of providing you with
11 information on our new policies coming out over the next year.
12 That's all I have. I'd be happy to answer any questions.

13 DR. LaFORCE: One question, have you ceased the
14 anthrax vaccination program for Canadian Forces?

15 LtCOL. FENSOM: Yes, we have, pending any further
16 activity in the Gulf, and we also are still awaiting the courts-
17 martial appeal on that very public case we had, and I'll
18 certainly bring that information to the Board when that appeal is
19 done.

20 DR. LaFORCE: Super. Thank you. Let's take a 15-
21 minute break, and then we'll reconvene and then continue the
22 program with the influenza reports. Thank you.

23 (Whereupon, a short recess was taken.)

24 DR. LaFORCE: There's been a switch in the program
25 and we are going to move on to the Bovine Spongiform Encephalitis

1 presentations, and then we will finish with the influenza
2 presentations. And let's begin in terms of the veterinary
3 issues, Col. Severin, Deputy Director, DoD, Veterinary Service
4 Activity. Col. Severin.

5 COL. SEVERIN: Thank you. Good morning. As you
6 said, I'm Col. Scott Severin, the Deputy Director of the DoD
7 Veterinary Service Activity, and I want to talk with you a few
8 minutes this morning about the impact BSE has had and continues
9 to have on the military.

10 (Slide)

11 There have been three main efforts where DoD has
12 focused its efforts in regards to BSE -- issues surrounding food
13 procurement, issues surrounding the DoD blood supplies which Maj.
14 Alford will speak to in the next presentation, and efforts to
15 provide consumer awareness.

16 (Slide)

17 Service members have four sources of beef while
18 stationed in Europe. They can eat in military dining facilities,
19 they can purchase products at the commissary stores which are
20 DoD's version of a grocery store, they can also make purchases at
21 exchange outlets which include convenience stores, cafeterias,
22 snack bars and concession operations, and they can eat on the
23 local economy. Since this is an individual choice, information on
24 the source of beef purchased for personal use and the frequency
25 of consumption is not available.

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(Slide)

Soldiers eating in military dining facilities were eating beef from the United States. Throughout this discussion, I'm going to talk about beef, even though all ruminant animals are capable of passing BSE. The same is true for operational rations, which include the MREs which are the Meals Ready to Eat, tray packs which are heat-and-serve type of multiperson serving container, and hot meals prepared in the field.

(Slide)

When you look at the other sources for food in Europe, local contracts must be discussed. It should be noted that the contracting agencies were contacted for their procurement data, and this was compiled by the Army Office of the Surgeon General based upon the dollar value of these contracts. These records are only kept for one to five years prior to being destroyed. Since we had to look back 20 years, approximations were provided by these agencies.

The Defense Logistics Agency, indicated as DLA on these slides, contracted for beef in Europe under the Off-Shore Beef Procurement Program. For carcass beef and boxed beef, the procurement specification did require that beef shall be free of all spinal cord. This does not mean that if an animal was inspected and found to have spinal cord present, that it would be rejected. All this means is that if it was present, it was considered a defect, and depending upon other defects found on

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1 the veterinary inspection, they may have negotiated a price
2 adjustment on that individual carcass.

3 These contracts also excluded ill or "downer"
4 cattle. A downer cow is an animal that cannot rise on its own.
5 This could be due to numerous etiologies -- muscle disease,
6 nutrition, fractures, CNS type disorder -- and also to meet the
7 requirements of our contracts we specified a younger animal. The
8 majority of the cattle that are slaughtered in Europe are older
9 dairy cows.

10 (Slide)

11 Two specific actions were taken by DoD in response
12 to BSE. In March of 1996, within days after official
13 notification of a probable link between BSE and Variant CJD, DoD
14 stopped procurement and sale of beef from the U.K. and other
15 countries with confirmed cases of BSE.

16 In March of 2000, in response to the emergence of
17 BSE in additional European countries and changes to U.S. import
18 laws, the Army Surgeon General banned procurement of all ruminant
19 meat and meat products of European origin.

20 (Slide)

21 The Commissary Agency does not do its own
22 contracting. As I mentioned earlier, DLA provided contract
23 support for all European procurement. During the 1980 to 1989
24 time frame, beef procurement averaged 2.5 million pounds monthly.
25 Thirty-five percent of this amount was from the U.K., and 65

1 percent was from other European countries. Of the U.K. product,
2 approximately 300,000 pounds monthly was delivered to commissary
3 stores north of the Alps, which are Germany, Belgium,
4 Netherlands, and the U.K., and approximately 575,000 pounds
5 monthly went south of the Alps to commissary stores in Italy,
6 Spain, Greece, and Turkey.

7 These contracts were written on a monthly basis,
8 thus, the source of supply to a specific store could change, and
9 did change, monthly. And as already noted, records no longer
10 exist. This made it impossible to determine which stores
11 received U.K. beef, and the assumption has to be made that all
12 stores received some U.K. product. These contracts were for
13 carcass beef which was split into four quarters at the packing
14 house, and further processed into retail cuts at the individual
15 meat markets.

16 (Slide)

17 In 1990, the Beef to Europe Program was initiated
18 for the commissary stores north of the Alps. This program
19 entailed shipment of boxed beef of U.S. origin to Europe. This
20 program was congressionally mandated and not related at all to
21 BSE. On the occasion of a supply failure, emergency purchase was
22 done within Europe and 99 percent of these contracts came from
23 Germany.

24 All commissary stores within the U.K. participated
25 in the Beef to Europe Program, with the exception of the Edsal

1 Commissary in Scotland. Shipments to the Edsal Commissary and
2 areas south of the Alps continued to be U.K. carcass beef. These
3 contracts converted to boxed beef in 1994, and as stated earlier,
4 after March 1996, all procurement of U.K. beef ended.

5 (Slide)

6 AAFES, which is the Army and Air Force Exchange
7 Service, was not able to provide any information on actual
8 amounts of pounds of product purchased. They did use similar
9 carcass cuts of meat, and they did use similar distribution
10 patterns as the Commissary Agency.

11 For use within their food service outlets,
12 approximately 20 percent of all beef used did come from the U.K.,
13 and when we look specifically at hamburger franchises, prior to
14 the reduction of troop strength in Europe there were over 50 of
15 these operations run as concessions. These operations used pre-
16 formed patties from the U.K. through 1989, and then from March
17 1990 to March 2000 either patties made solely from U.S. beef or
18 patties that were made from a combination of U.S. and non-U.K.
19 beef were ground in an AAFES-operated grinding facility in
20 Germany.

21 Between March 1996 and March 2000, most beef
22 originated from European countries without cases of BSE, and some
23 did come from the U.S. Since March 2000, all beef has either
24 come from the U.S. or from non-European origin sources.

25 (Slide)

1 As I mentioned earlier, living on the economy is
2 an individual choice, and so information of the sources of beef
3 purchased and the frequency of consumption is not known.
4 However, DoD has used numerous media to inform consumers of the
5 risks associated with consuming U.K. beef.

6 (Slide)

7 The CDC estimate of current risk has been part of
8 our consumer awareness products. This risk estimate was updated
9 by CDC in January of 2001.

10 (Slide)

11 In addition to providing consumers with CDC's risk
12 estimate, we also provided them this portion of the Traveler's
13 Advisory, which recommend avoidance if consumers are concerned
14 about eating beef in Europe.

15 (Slide)

16 Due to the supply lines used by DoD, service
17 members in Southwest Asia or CENTCOM have also had the potential
18 to be supplied with beef from the U.K. and Europe. Unlike
19 Europe, not all product for troop dining was of U.S. origin.
20 From 1990 to 1996, Military Dining Facilities used beef
21 originating from several countries, including the U.K.

22 As in Europe, policy excluded U.K. beef after
23 March of 1996, and all European beef after March of 2000. The
24 Commissaries and Exchange outlets are supplied from military
25 sources within EUCOM, thus, the contracting patterns would be the

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1 same as discussed in the earlier slides.

2 (Slide)

3 This slide summarizes the total number of service
4 members and their families who resided in Europe during the
5 periods when U.K. beef was being supplied to Continental Europe.

6 Because of the differences in supply to the Commissary stores,
7 data is provided showing residents north and south of the Alps.

8 (Slide)

9 This slide summarizes the number of individuals
10 from the prior slide who are still on active duty or who have
11 dependents.

12 (Slide)

13 These are the main goals of the Consumer Awareness
14 Program which was developed this past winter to protect the
15 health of our military forces, to sustain the confidence of our
16 service members and the Military Health Organizations, to inform
17 our service members and their families of the risks associated
18 with BSE, but not to raise their level of concern unnecessarily.

19 (Slide)

20 The first message is that the health and safety of
21 the DoD community is our primary focus. Actions have been taken
22 to further minimize a very small risk, and accurate information
23 will be made available to the DoD community to enable them to
24 make informed decisions.

25 (Slide)

1 The second message is that the food and blood
2 supplies are safe.

3 (Slide)

4 The third message is that DoD is coordinating with
5 other Federal public health agencies to ensure the most accurate
6 and up-to-date information is available. Our primary
7 coordination has been with the USDA, the FDA, and CDC.

8 (Slide)

9 These are examples of the actions that we've
10 completed at this point. We have put a consumer awareness packet
11 on the CHPPM Web page, and it provides both information for
12 consumers as well as health care providers.

13 (Slide)

14 And this is an example of one of the fact sheets
15 that was developed for CENTCOM. Thank you for your attention.

16 DR. LaFORCE: Questions? I would ask, has a
17 survey been done to actually determine how extensive access was
18 to European beef amongst either forces or their dependents?

19 COL. SEVERIN: No surveys have been done that I'm
20 aware of, but if you're talking about consuming on the local
21 economy, one of the benefits of being in Europe is being able to
22 go overseas and partake in the local festivities.

23 DR. LaFORCE: No, no, no, that's not the point. I
24 fully agree with you, they cook well, but the point that I was
25 saying is that rather than saying there is no knowledge, I mean,

1 it would seem that a survey questionnaire could be designed to
2 actually try to access what fraction or how often those sources
3 are used.

4 COL. SEVERIN: Well, from the standpoint of our
5 service members that had their families there, almost all the
6 food they consumed was bought from the Commissary stores, and a
7 third of their beef came from the U.K. From the standpoint of
8 going to the Burger King or the snack bar, all of their burgers
9 from 1980 to 1989 came from the U.K. So, every time you went to
10 Burger King, you were getting a U.K. burger for that ten years.
11 After that, it was U.S. or non-U.K. beef. From the standpoint of
12 the concessions, the other types of concessions, which would be
13 the cafeterias, some of the other snack bars, 20 percent of that
14 beef came from the U.K.

15 The only beef that we can say for sure that was
16 not U.K. beef was what was consumed in the dining facility, the
17 military-run dining facility. You can ask single soldiers how
18 many times they ate there, but a lot of them would rather go
19 downtown to Burger King than eat in the dining facility, even
20 nowadays. So, you're going to get a skewed response no matter
21 what type of survey you do.

22 DR. LaFORCE: Other questions? Yes?

23 DR. LANDRIGAN: Two things. First of all, you
24 said that the current estimate of risk was 1 per 10 billion. I
25 was curious --

1 COL. SEVERIN: Less than 1 per 10 billion
2 servings.

3 DR. LANDRIGAN: Yes, sir. Has that changed over
4 time?

5 COL. SEVERIN: No, and that's -- the way CDC has
6 worded that risk is they say -- it has not changed since CDC
7 first came up with it. The only qualifier to it is -- and I can
8 read it to you -- "In the United Kingdom, this current risk
9 appears to be extremely small, perhaps about 1 case per 10
10 billion servings. In other countries of Europe, this current
11 risk, if it exists at all, would not be likely to be any higher
12 than that in the U.K., except possibly Portugal. In the 12-month
13 period ending June 15, 2000, Portugal had about half the reported
14 incidents of BSE cases per 1 million adult cattle as that
15 reported in the U.K. However, Portugal has less experience with
16 implementing the BSE-related public health control measures."

17 So, they have not changed it. When I talked with
18 CDC, they based that upon estimates that allowed a tenfold factor
19 one way or the other. So, it really could be from 100,000 to 1
20 in 1 billion to 1 in 100 billion servings.

21 DR. LANDRIGAN: And my second question is whether
22 you've put into place any sort of surveillance system to track
23 folks who are still there and folks who have come back?

24 COL. SEVERIN: We have not put a surveillance
25 program in place. That was mentioned at the BSE Advisory

1 Committee meeting six months ago. It was asked, but there has
2 not been one in place at this point. Most of our individuals are
3 going to show with a Variant-CJD are going to be out of the
4 military when they actually do show signs of disease.

5 DR. LaFORCE: Kevin?

6 DR. PATRICK: I don't want to take this too far
7 afield, but I'm wondering what sort of general nutrition and
8 dietary behavior surveillance system is going on among these
9 personnel, both active duty and families, if any?

10 COL. SEVERIN: I'm not sure. I know the
11 nutritionists would be better able to answer that than I am. I
12 know they do some surveys, but as to the full extent, I have no
13 idea.

14 DR. PATRICK: There's sort of the implicit
15 assumption that beef consumption is just going to continue to be
16 stable and --

17 COL. SEVERIN: When you compare beef consumption
18 of U.S. Forces in Europe versus the European community as a
19 whole, we're staying stable where the EU consumption has dropped
20 because of the BSE scare. That's probably very good indication
21 that our Consumer Awareness Program is working and folks do
22 realize they are getting U.S. beef now.

23 DR. LaFORCE: Bill?

24 DR. BERG: Bill Berg, Hampton Health Department.
25 What's your basis for saying that most of the people are likely

1 to be out of the military and surveillance is not worth it? My
2 understanding of new Variant-CJD is that one of its
3 characteristics is that cases can come on relatively quickly
4 within a few years. Now, if most of the troops over there are on
5 their first tour and they are likely to leave right away, then
6 that might be the case, but -- it's not a frequent disease, but
7 you might be able to catch some.

8 COL. SEVERIN: We've provided information to the
9 neurologists, the family care practitioners. This type of
10 information has been provided by our neurology consultant, so
11 they are aware to look for it if someone presents with the
12 symptoms that would match a Variant-CJD case. If you remember
13 back to the slide of the demographics, there were 4.5 million
14 people in that 1980 to 1996 time frame. Only 500,000 of those
15 still are within the active duty rolls. So, that's one-ninth of
16 the population is all that's left on active duty.

17 COL. BRADSHAW: The problem is not, I think, with
18 the active duty because through the Defense Medical Surveillance
19 System, if they are hospitalized in one of our hospitals, we
20 would get that through the standard inpatient data record, as
21 long as it's coded properly.

22 The issue is probably with those that have left
23 the service, and then we have to do it the same way that the rest
24 of the country does it, and I think there is a group that
25 collects CJD cases and kind of has their own little registry, and

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1 then CDC, I believe, is also tracking it. In the Air Force, we
2 have an Air Force Mortality Registry that we also collect those
3 kind of diagnoses with a nosologist and so on, and there is a
4 move to get a DoD kind of mortality registry going, but that's a
5 little bit further out. But we do have some limitations, but if
6 they are on active duty, we should be able to catch it as long as
7 it's coded.

8 DR. BERG: Even though that's only one-ninth
9 remaining, that's still about 500,000, if I heard you correctly.

10 COL. SEVERIN: Yes, it is.

11 COL. BRADSHAW: And today we have not, at least in
12 the Air Force, had any, nor has CDC.

13 COL. SEVERIN: There have been no cases of
14 Variant-CJD in the United States or in our military population at
15 all. And you are right, there is a national CDC registry, and
16 the individual that runs that lab has used the majority of slides
17 looking for potential Variant-CJD cases.

18 DR. LaFORCE: Let's move on. Next presentation,
19 Maj. Ronny Alford, on Deputy Director, Armed Forces Blood
20 Program.

21 MAJ. ALFORD: Good morning. Maj. Alford, from the
22 Armed Services Blood Program Office. I'll be giving you an
23 update in terms of vCJD and the blood supply for DoD.

24 (Slide)

25 A little bit of background. In DoD today, we

1 collect about 120,000 units of blood a year. We have deferrals.

2 The FDA required deferrals for vCJD that were in place as of
3 February of last year, and those precautions are that any
4 perspective donor that has spent more than six months cumulative
5 time in the U.K. from 1980 to 1996 are not eligible to donate
6 blood to us.

7 When we implemented that policy last year, that
8 knocked out about 10 percent of the Air Force's blood donor
9 population. We had a huge problem getting blood at the Donor
10 Center at Lakenheath for a few months, until some of those folks
11 PCS'd out and we got some new people in.

12 The other requirements that are current from FDA
13 is that anyone who has taken bovine-sourced insulin that's U.K.
14 derived, and dura mater transplant as another source of deferral.

15 (Slide)

16 The current players in the U.S., the America's Blood Centers are
17 the largest, they collect about 47 percent of the U.S. blood
18 supply; American Red Cross collects about 45 percent; DoD, we are
19 a very thin slice of that pie, we're only about 1 percent.
20 There's about 13 million donations in the U.S.

21 I put that up there because there's much debate
22 going on today in regards to what's going to happen locally in
23 the U.S. in terms of additional deferrals.

24 (Slide)

25 We have been told by FDA that there will be

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1 additional deferrals. Col. Severin alluded to the TSEAC meeting
2 of January. There's another scheduled for next month. From the
3 meeting in January, the recommendation from the Advisory
4 Committee was that additional deferrals for travel and residents
5 be put in place, and the recommendations was a cumulative of 10
6 years residency in France, Portugal, and Ireland. I'm fairly
7 sure that's what's going to fall out next month will be
8 significantly more restrictive than that.

9 The Red Cross has proposed something significantly
10 more restrictive. As of yesterday, on ABC News, if anyone
11 happened to catch that last night, Red Cross publicly stated that
12 in September they will be implementing donor deferrals for anyone
13 who has spent more than three months in the U.K. since 1980 to
14 date, and more than six months in Europe 1980 to date.

15 We've been in discussions with the Red Cross in
16 terms of what their definition of Europe is. One of the
17 definitions that we were given was that anything west of the
18 Urals. Another definition is the FDA's list of BSE countries
19 that are on the BSE list. We think that they are probably going
20 with the USDA list, but that has not been finalized as of yet.
21 Again, they are planning to implement in September.

22 (Slide)

23 So, huge differences between FDA and Red Cross.
24 We think that probably the biggest reason for that is the risk of
25 transmission is theoretical, and in the lack of scientific

1 certainty, we just don't know.

2 Whenever we speak to anyone from the Red Cross,
3 that perfect little article from Lancet 2000 is tossed out, and
4 there is one study that was suggested of transmission via
5 transfusion in a sheep model.

6 Obviously, we in DoD are incredibly concerned
7 about a two-tiered standard because it really places us in a very
8 difficult position in terms of meeting our readiness
9 requirements. We've been told that the standard of practice will
10 be the driving force for us. We will meet standard of practice.

11 (Slide)

12 There are, again, additional discussions of Health
13 and Human Services and DoD coming out with different standards.
14 I don't think that that will actually happen. We will go with
15 the stricter standard. We were given those marching orders from
16 Dr. Clinton and Mr. Kragan.

17 FDA is working with the Red Cross on a compromise
18 for these standards. Who knows what's going to happen with that,
19 but we stand at the ready to assist, if asked.

20 The reason I tossed up those initial slides just
21 letting you know that the largest organization in the U.S. is the
22 American Blood Centers is that the American Blood Centers do not
23 plan to implement policies stricter than those recommended by the
24 Food and Drug Administration, hence the discussion of the two-
25 tiered system.

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1 (Slide)

2 As Col. Severin mentioned, the availability of
3 U.K. beef in EUCOM commissaries, roughly 35 percent. What we've
4 been told by the FDA is that in the final deferral guidelines
5 that will be coming out in a matter of weeks, in addition to the
6 regular civilian deferrals there will be a military-specific
7 deferral based on the availability of the U.K. beef in the
8 commissaries.

9 What they are looking at -- they, being FDA -- is
10 18 months for personnel and their families stationed in Europe
11 only during the times that the beef was available in the
12 commissaries.

13 A major distinction there with what the American
14 Red Cross is proposing is that their deferrals go to date. There
15 is no end point for theirs.

16 The FDA's discussions with us regarding tightening
17 down their TSEAC recommendations is that they are considering
18 with a three-year travel or residency ban for Europe, and FDA is
19 looking at the USDA BSE list in terms of defining Europe. So,
20 still significant gap there between Red Cross and FDA.

21 (Slide)

22 The deferrals will be stricter for our personnel
23 who were stationed south of the Alps, and it's only because of
24 the length of time that the U.K.-derived beef was available to
25 them.

1 As of today, about 8 percent of the active
2 component is stationed in EUCOM today.

3 (Slide)

4 I just tossed this slide in to kind of give you a
5 feel for where our people are, what countries they are stationed
6 in. Seeing as how we will be going with the actual list from
7 USDA and in addition to that the availability of the U.K. beef,
8 then this slide really becomes irrelevant because it really
9 doesn't matter if you were in Germany or Netherlands or wherever,
10 if the commissary beef was coming from the U.K.

11 (Slide)

12 The USDA BSE List, the current list.

13 (Slide)

14 The proposals -- and this is only effective within
15 DoD. Going with the Red Cross proposal, we will lose about 25
16 percent of our donor base across-the-board. Going with the FDA
17 proposal, we'll lose about 18 percent of our donor base, the
18 largest impact being on the Army, the least being on the Navy.

19 What we found when we ran the tapes that we
20 received from DMDC with the assignment histories going back to
21 '86 was -- as far as they could take us on those tapes -- the
22 deferral timelines were really insignificant, whether we're
23 looking at 6 months, 12 months, 18 months, because unaccompanied
24 tours in Europe are 24 months, so any deferral that doesn't peak
25 24 months, it makes no difference to us. So, we -- again,

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1 bearing in mind that FDA has told us we will defer anyone with 18
2 months.

3 Of course, we are obviously very concerned about
4 the public perception and implied safety claims of "our blood is
5 more safe than their blood" kind of a deal.

6 You can scratch the 6 percent on the last line.
7 We are looking at a 12-percent donor loss within the U.S.
8 civilian population. I'm sure you really don't have to look very
9 hard to see or to hear the screams for donors during the summer
10 months, during Christmas. The availability of blood will become
11 a significant issue for the country once these -- if the Red
12 Cross actually presses forward and implements their policies.

13 (Slide)

14 Some of the things that we've done to try to come
15 to terms with the issues with the Red Cross and the ABC in terms
16 of what we will be doing in DoD. Dr. Clinton has met
17 individually with the Red Cross and Americas Blood Centers to
18 give them our position, and that is that we will meet standard of
19 practice. We back in the Blood Program Office have hosted
20 strategic planning conferences to try to figure out exactly how
21 we can overcome that loss of one-fourth of our eligible donors,
22 and then we just have to really understand that we cannot depend
23 on civilian blood support in the future, not on short notice
24 anyway, because the products just aren't available.

25 (Slide)

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1 What we will be doing to begin to get over the
2 hurdle is that we're basically going to optimize blood
3 collections at training bases, the "bleed them before we deploy
4 them" concept, perhaps restricting access to some of our DoD
5 locations. We have an awful lot of -- Red Cross collects more
6 blood off of DoD facilities than the Armed Services does, and
7 that's only because we just really have no need to have a donor
8 center in Great Falls, Montana, although we have a base there.

9 We looked at the Pentagon as a prime example. The
10 Red Cross actually sets up and has a permanent shop there. I
11 don't think they're going to get many donors out of the Pentagon
12 once they press forward with that new policy, so we'll let them
13 keep the Pentagon. And then modifying MOUs with civilian
14 agencies. DoD does not have the donor collection capacity to
15 meet a short-notice MERCK (phonetic) type of scenario, we have to
16 rely on getting blood from the civilian agencies. So, we're
17 looking at a system here in a couple of months of perhaps having
18 roughly half of the nation's blood supply being produced with the
19 FDA standard and the other half being produced with this other
20 standard, and we feel that we have to have all of the blood being
21 produced under one standard.

22 (Slide)

23 I'll leave you with the last thought, and that is
24 we can certainly meet our peacetime blood requirements just by
25 reorganizing our donor center efforts onto the training bases.

1 We will have to do a good bit of additional recruiting to replace
2 that 25 percent of loss donors, but it can be done and the plans
3 are in the works to make it happen. That concludes my briefing.

4 Any questions?

5 DR. LaFORCE: I may have missed this when you were
6 saying it, but when you look at the amount of blood that's
7 collected in the Armed Forces, are you a net-plus or a negative
8 at the end of the year? In other words, you're able to meet all
9 of your needs?

10 MAJ. ALFORD: We are a net-plus.

11 DR. LaFORCE: By a lot or a little?

12 MAJ. ALFORD: By about 30,000 units, about 25
13 percent.

14 DR. LaFORCE: So it's a lot.

15 MAJ. ALFORD: About 25 percent.

16 DR. LaFORCE: So your requirement is about 100,000
17 units per year?

18 MAJ. ALFORD: Right, of transfused product, but we
19 wind up purchasing a lot of blood because our major donor centers
20 are at the places -- the training bases right now, really, and I
21 guess larger troop concentrations. We don't really have large
22 donor centers servicing Bethesda, servicing Walter Reed, so those
23 places will wind up having to purchase blood occasionally to meet
24 short-notice type of requirements -- you know, irradiated
25 platelets or HLA-matched product and those types of things. So,

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1 we do purchase some 20,000 or so units a year within DoD. By the
2 same token, we sell some of our short-dated units as well to go
3 out to the trauma centers rather than allowing it to expire on
4 the shelves.

5 DR. LaFORCE: I hate to make this sound like a
6 business, but is that a break-even proposition, or do you lose
7 money?

8 MAJ. ALFORD: Wow. Difficult question to answer.

9 DR. LaFORCE: No, it's an important question from
10 the standpoint in terms of the recommendations. In other words,
11 do you really make an effort at trying to collect all the units
12 within the military rather than giving all of those away, as you
13 currently are?

14 MAJ. ALFORD: We would lose. It's a money-losing
15 proposition from that standpoint because -- it's a money-loser
16 for us because the products that we wind up purchasing are very
17 specialized, very expensive products, you know, things that --
18 granulocytes for some of the chemo patients occasionally, and
19 those things are just incredibly expensive, but we don't really
20 have a Center of Excellence, if you will, that require that type
21 of product on a routine basis, so we have to go out to the
22 civilian community for those.

23 DR. LaFORCE: Other questions, observations?
24 Joel?

25 DR. GAYDOS: Joel Gaydos, with the Department of

1 Defense Emergent Infection System. Does the Department of
2 Defense purchase any blood from foreign countries?

3 MAJ. ALFORD: Occasionally, under emergent
4 situations, there is guidance that allows blood products to be
5 purchased in OCONUS locations if U.S. products aren't available.
6 And then we have some additional requirements such that requires
7 additional testing to be performed on the units that were
8 purchased, if that can be accomplished. If not, then there's
9 follow-up of the patient for additional testing.

10 DR. GAYDOS: So that contingency still exists in
11 Europe in the event that blood is needed.

12 MAJ. ALFORD: Yes.

13 DR. GAYDOS: And my understanding is that we have
14 a fairly large number of DoD beneficiaries who are receiving
15 inpatient care in European facilities, health care facilities.

16 MAJ. ALFORD: I don't know if it's a large number,
17 I know that it does occur.

18 DR. GAYDOS: Has there been anything happening
19 with regard to any of these individuals who may require blood
20 declining to use those facilities?

21 MAJ. ALFORD: I'm sorry?

22 DR. GAYDOS: Has there been any impact from the
23 people who would be using those facilities and having procedures
24 that may require use of blood, decline to use those facilities?
25 Has there been anything sent out to the beneficiary population in

1 the way of information about using those facilities?

2 MAJ. ALFORD: Not yet. There are some -- the
3 educational campaign that CHPPM is spearheading, it has the
4 information that's being targeted to hospital commanders
5 informing them of the risks. We haven't gotten any feedback yet,
6 whether or not that's being an issue.

7 DR. LaFORCE: John?

8 DR. HERBOLD: John Herbold, San Antonio. If we
9 can get back to the meat procurement a little bit, I'm not sure
10 if it's a risk assessment or a risk communication question, but
11 it struck me when we were trying to talk about evaluating the
12 potential risk for troops and their dependents stationed in
13 Europe of developing a variant CJD and looking for it, that there
14 might be a difference in two groups over there that a nutrition
15 habits survey would help support.

16 If memory serves me right, the carcass beef
17 procurement, I think as was mentioned by Col. Severin, is half or
18 quartered beef that was bought on the market in the U.K., and
19 then it's those quarters or slabs are sent to each commissary
20 where butchers in the traditional sense prepare the cuts of meat,
21 and then the trimmings and things are used for hamburger and
22 those things. And the risk, the potential risk, if the
23 biological theory is correct, for variant CJD would go with
24 eating consuming organ meats and mechanically deboned hamburger,
25 which does not occur, or did not occur, amongst the commissaries.

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1 So, the beef that ends up in the commissary has
2 been trimmed of a lot of things, and the organs have gone on to
3 the economy in the U.K., and the carcasses are not mechanically
4 deboned, which adds more nervous tissue to the hamburger. So, it
5 seems to me that the hypothesis would be that for those
6 dependents and active duty people who consumed U.K. procured beef
7 purchased from the commissary would be less likely to be victims
8 of variant CJD than those active duty folks and dependents who
9 purchased and/or consumed more product on the economy.

10 And then as Dana alluded to, I also think that
11 when you're looking for clusters, the question is going to emerge
12 in 15 or 20 years when you have several 30-year-olds break with
13 some type of what's identified as a TSE, and then the question is
14 -- and they are military-related, and then the question becomes
15 were there more of them that were stationed in Europe at the time
16 of the "mad cow" disease scare. But it's a natural experiment
17 that's there, but it wouldn't be good -- you wouldn't be able to
18 do it unless you got the nutritional habits information now.

19 We did a survey of a CJD cluster in East Texas, in
20 Tyler, Texas, and it had nothing to do with the military, but it
21 was a cluster in geography, it was in one county, and it was a
22 cluster in time that there was an excess of deaths. And it was a
23 cluster in that the average age of the folks that died of CJD
24 were a little bit younger than what would be expected normally.
25 And as usually goes with clusters, we had six deaths, and so we

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1 did a 4-to-1 match and we had 30 people in our study, and we put
2 together a food history that went back six decades, and it took
3 two and a half hours to conduct one survey on the telephone, and
4 I did a couple of them -- I'm glad I only did a couple of them --
5 because what we learned from that pilot effort was that was not
6 the way to do it, and we couldn't answer the question. But there
7 might be some food for thought here, if there is any type of in-
8 hands database available for military folks.

9 And then, also, the question that comes to my
10 mind, since I'm on the other side of the fence now, is there a
11 seamless interface between surveillance of active duty related
12 folks and then those who have a history of service with the Armed
13 Forces -- you know, like a national death index of some type.

14 DR. LaFORCE: I was going to ask, Col. Warde,
15 whether you might have any insights, given the fact that they're
16 talking about U.K. beef?

17 COL. WARDE: Well, I'm really following this story
18 with a closer than average interest, having lived through all
19 this, although I did serve most of my time in the '80s and '90s
20 in Germany and overseas, which I am very grateful. But actually
21 it is not a lighthearted topic, and it is getting to the point
22 where comments like the fact that I'm quite glad that my blood is
23 no use to you, things like that, is wearing a bit thin because
24 one of these days I shall meet somebody who has had a victim in
25 their family, and then, of course, I shall regret having said

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1 anything like that.

2 But I'm watching all these comments. I feel that
3 everything that has been discussed here has been done with the
4 best intentions. It's all been extremely logical. I think all
5 the precautions that have been taken by the USDA, by the DoD, are
6 absolutely right. Nobody would wish the experience that the U.K.
7 has had to be experienced anywhere else, and I cross my fingers
8 every day as I read the papers in the hope of seeing no new
9 developments which would lead us to think that the epidemic which
10 is currently 99 cases in the U.K., is going to grow any quicker.

11 Nothing that I have heard this morning has
12 prompted me to sort of throw any new light on the discussion.
13 The facts are extremely well known, and I know that Col. Severin,
14 for example, and I have discussed this regularly and we compare
15 notes, and it is a tense time actually to see what is going to
16 happen in Europe and to see how this epidemic will pan out.

17 I mean, last week, there was the suggestion that
18 victims so far have been all of one genotype and that there may
19 be a possibility of other genotypes becoming susceptible but with
20 longer incubation periods. That's a very shocking thought. I
21 take comfort from the fact that I think that in sheep and in
22 cattle, the genetic susceptibilities, although not completely
23 worked out, is definitely a key to understanding susceptibility
24 to transmissible spongiform encephalopathy, and that there isn't
25 yet any evidence that the other genotypes in humans are

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1 susceptible. Apparently 40 percent of the U.K. population has
2 the genotype which is susceptible. That's enough, thank you very
3 much.

4 DR. LaFORCE: Thank you. Other questions,
5 observations? I really am struck that this may, 20 years from
6 now or 30 years from now, come to nothing -- in other words, no
7 epidemic -- but I'm also just as sanguine in terms of saying 20
8 or 30 years from now we may have a cluster of cases who served
9 over -- and it's going to be -- that's why I asked the question
10 about the food histories. That may sound pedestrian and sort of
11 mundane, et cetera, but that's the kind of information that if
12 you have it at least filed away, you've got something that you
13 can refer back to because having done food histories back as long
14 as like two or three weeks ago, it's hard to get a decent food
15 history two or three weeks ago, let alone two or three decades.

16 So, I'd just -- my sense -- and I really would
17 like to throw this out to the Board -- that I would think maybe a
18 little bit more investment, and not expensive stuff, but a little
19 bit more investment in terms of information now may be of great
20 value to you 20 years from now should something happen and should
21 you need a case control study, or should you need some more
22 information in terms of dietary activities of individuals who
23 were in Europe. That's all. Yes, Ken?

24 CAPT. SCHOR: This is more directed at the blood
25 supply issue. If we're bearing the brunt of a policy that may

1 not be well founded on science, which is I think what you said,
2 and if the brunt of that burden is maldistribution of current
3 supplies, we can meet our current needs for units, that begs the
4 question of readiness should there be some level of contingency
5 and increased demand for blood.

6 So, therefore, at that point do we go screaming
7 and say, well, let's just change the policy, which creates a lot
8 of problems. I guess even though we are a small user of the
9 overall blood supply, like we are in many other things like
10 vaccines, I wonder how we can raise this to a level of -- to an
11 appropriate level of national security issues. If it threatens
12 our ability to respond to contingencies and meet increasing
13 demands, then maybe we need to articulate that need more
14 forcefully and deal with that up front, rather than having to
15 deal with it after-the-fact.

16 MAJ. ALFORD: The availability, or the impact on
17 availability of blood for DoD is being raised at the highest
18 levels -- Cabinet-to-Cabinet level -- that is occurring.

19 CAPT. SCHOR: And did they have the visibility --
20 you know, I would assume that the CINC Surgeons that would be
21 responsible for responding -- you know, I don't know what level
22 of concern they have for it, but I'm sure there must be some.

23 MAJ. ALFORD: A very high level. Unfortunately,
24 with the developments from just last night -- I'm sure when I get
25 back to the office, as soon as I get back to the Beltway, I'd be

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1 able to call you up and give you a much better feel for what's
2 going on.

3 In terms of being able to get blood into DoD from
4 outside sources, we have contingency contracts with the Red
5 Cross, with Americas Blood Centers. The concern for us, and with
6 the CINC Surgeons -- and this will be raised to them, I guess,
7 next week -- is that there will be these two systems, these two
8 bars, one perceived to be lower than the other. And it may very
9 well turn out that it really doesn't matter, it's just a
10 theoretical risk. However, if 20 years or however it turns out
11 to be a risk or to be an issue, then we just want to ensure that
12 we've taken all the precautionary measures that are prudent or
13 warranted.

14 So, again, the blood, getting additional blood in
15 would be possible, it would just be the decision to use the FDA
16 standards versus the Red Cross' additional standard of practice
17 standards. That decision would be made at a very, very high
18 level.

19 DR. LaFORCE: Okay. Thank you. Let's move on to
20 the presentations on Influenza Survey Summary. This is Ms.
21 Canas, the Chief of Diagnostic Virology, from the Air Force. You
22 recall her presentation, I believe it was a year ago --

23 MS. CANAS: Two years.

24 DR. LaFORCE: -- two years -- how time flies -- in
25 terms of influenza in the military.

1 MS. CANAS: Good morning.

2 (Slide)

3 The Department of Defense Influenza Surveillance
4 Program that operates under the support of the Global Emerging
5 Infections System, continues to grow in scope and importance. Of
6 the three influenza components, vaccine components, in this
7 year's vaccine, two were directly impacted by this program.

8 (Slide)

9 There are two parts to the program now. It is
10 triservice. NHRC in San Diego operates the population based
11 surveillance which collects samples on a rate-basis from all of
12 the Recruit Training Centers. At Brooks Air Force Base, we have
13 operated -- actually, the program has operated there since 1976,
14 under the direction of the Air Force, and it was known as
15 "Project Gargle", and we're out there basically just trolling for
16 bugs. Whatever we can find, from wherever it comes in, we're
17 looking for it and we are going to report it.

18 And to give you an idea, there's probably several
19 Board members who don't know just how this program works. So to
20 give you an idea of what we do, each fall the epidemiologists and
21 the laboratorians at Brooks get together and we decide if there
22 are going to be any changes in the program over the past year,
23 and that information is sent forward to the Air Force Surgeon
24 General who makes decisions and sends out the annual letter each
25 year which will mandate that all of the active duty individuals

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1 will be vaccinated and, at the same time, he names the sentinel
2 sites.

3 The laboratory makes sure that all the supplies
4 are available and all instructions are in place for how to ship
5 these specimens. Generally, it's the Public Health Officer at
6 each installation who makes sure that these samples are collected
7 and are sent to the laboratory.

8 Now, I need to also explain that our laboratory is
9 a full-service reference laboratory, so this is not operating in
10 a vacuum. We have FedEx contracts for virtually all of our Air
11 Force military treatment facilities and several other -- the Army
12 and Navy are also able to utilize this when they are sending us
13 clinical samples and these respiratory samples are included in
14 those shipments.

15 And in the laboratory then, we do generally good -
16 - well -- always do good laboratory practices to isolate any
17 virus that's there and to report out. Now, each one of these is
18 entered into our database system as a patient history, and the
19 results then go back to the base as a patient reportable report.

20 But that may not go directly to the epidemiologist, so our
21 Epidemiology Department also gets that information, Col.
22 Neville's people, and they email back to the Public Health
23 Officer, so he has some kind of a real-time information about
24 what's going on in their facility. They can do follow-up on
25 those cases, to make sure any vaccination histories are put into

1 the computer system and, if there are any possible interventions,
2 they will be able to impact those also. And, of course, they can
3 collect all this information and do a variety of different
4 reports that always do come up.

5 We send an annual report each year to the GEIS
6 office, as well as to the various sites, and it goes up on the
7 Web site, and then from the laboratory, we do antigenic analysis
8 of the various influenza samples that we get, and selected
9 isolates are then sent on to CDC where determinations can be made
10 for vaccine composition.

11 (Slide)

12 And this is our map this year. We have in blue
13 are those military treatment facilities that we have had for many
14 -- we basically choose these for training sites where we have
15 many individuals who are coming together, and we are very
16 interested in their public health as well as surveillance. We
17 want to be able to intervene as quickly as possible if there is a
18 respiratory issue going on.

19 Now, Lackland is a Recruit Center, and they do
20 send samples on a rate basis to NHRC for inclusion in their
21 database, but we have a long historical association with them
22 sending samples, and we are in the same town, so they do tend to
23 send us quite a few samples from the individuals who are ill and
24 they want immediate update on what's going on.

25 We're also choosing sites on the coastline so that

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1 we're getting people who have been overseas and they may be
2 bringing with them a flu virus or another virus that they have
3 contracted overseas.

4 (Slide)

5 And then all of our overseas facilities. And I
6 would say that the Navy out of Pearl Harbor in the Pacific, has
7 been particularly helpful in soliciting and collecting samples,
8 and we've gotten a lot of good results and good information from
9 them. We've got some proposed sites in Honduras, Uganda, and
10 Bolivia. These are not online yet, but we're still working on
11 bringing them. There's always some unique political
12 considerations and logistical -- shipping is truly the weakest
13 link in this whole program, and it takes a lot of time to work
14 that out.

15 And the most exciting part of the program in the
16 last few years has been working with the Army and Navy Medical
17 Research Facilities overseas, over in Thailand, AFRAMS in
18 Thailand and Nepal, and with NAMRIID down in South America, where
19 they've been able to ship samples, and that takes a lot of effort
20 on many people's part in order to do those. And we often wonder
21 if the result is really worth it.

22 This is this season, what we have received from
23 samples that were collected after October 1st. We tend to get
24 these in -- we've had three shipments, and each of them have,
25 well, about 100 samples each, but sometimes the collection rates

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1 were sooner, so those were not necessarily included. But you can
2 see we've had a very good following of a case definition of
3 respiratory illness. We're getting very good results from these
4 samples, especially from Peru this year.

5 In Argentina, we continue to see Flu-B as it
6 increases this past year. Nepal has always been exciting, and
7 there is no surveillance in that area. CDC and the World Health
8 Organization considers this a particularly important site because
9 it's on that major trade route between China and India, where we
10 could possibly pick up something that's emerging in that area of
11 the world.

12 Thailand, we have been able to get samples from
13 the American Embassy from that area of the world. Ecuador, we
14 actually did get samples and isolates, but these had been from
15 last summer, so those were not included in this total.

16 And so 6 percent of all our samples came from
17 these sites. That represents a significant part of the program,
18 and also it establishes -- perhaps the most important,
19 establishing that infrastructure so that we can respond to
20 outbreaks, and we have in the past.

21 (Slide)

22 This is our graph from this past year. It pretty
23 much looks like any influenza season, with the peaks coming at
24 the proper times, in the January-February time frame. We have
25 the percent-positive that were isolated over on the right chart.

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1
2 The one very significant difference this year that
3 we very seldom ever see is that it was almost an equal A and B
4 year. Almost always we have a predominant strain. It has been
5 the H3N2 that may trail off at the end into a B, but to have this
6 many As and Bs at the same time is very unusual.

7 And, you know, you always wonder -- the scope of
8 our program, of course, is totally dependent on what we get in
9 from the sites. When I was reading the CDC Annual Update for the
10 United States for this past year, first of all, they said that 13
11 percent of the specimens that were submitted to their sentinel
12 positions were positive for influenza. So, I figured ours, and
13 we had 12.9 percent of ours. I didn't round it off just so it
14 could be different.

15 CDC also reported that 58 percent of their samples
16 were A and 42 percent were B. Ours were slightly different, we
17 had 44 percent A and 56 percent B, and I think that difference,
18 the increased B, is for two reasons: One, probably just the
19 artifact of surveillance. A lot of our sites may have been from
20 areas that they either didn't get as many or different areas of
21 the world all together. But perhaps another area is Influenza-B
22 is somewhat less severe than the H3N2-As that have been
23 circulating in the past. And because of the vaccine shortage that
24 we knew was a problem this year, there was increased awareness of
25 the importance of surveillance. I had many calls from commanders

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1 who were very concerned of what it would mean to their unit if
2 there was an influenza outbreak. So, I think our surveillance
3 started much earlier and probably included many more people that
4 may not have sought health care in the public sector. That's a
5 possible explanation for why we had more Bs, although it was a
6 very equal A-B year.

7 (Slide)

8 These are the numbers.

9 (Slide)

10 And in your handouts, the second page has each of
11 those broken out individually so you can read them a little
12 easier. We do look for, besides Influenza-A and B, we look for
13 adenovirus, herpes viruses, Parainfluenzas which right now we're
14 seeing quite a few Para-3s, enteroviruses. RSV is not a good
15 sample in this particular study. It's generally the pediatric
16 population. So, while we do get RSV requests, it's usually done
17 on-site. Ours is usually just confirmation of someone else's.
18 So, if we were to include RSV in this study, it would dwarf
19 everything else probably.

20 (Slide)

21 If we look at hospitalizations using the standard
22 inpatient registry data, this is just kind of to give you a
23 flavor of the impact on the health care program. These are the
24 rates that have been coded upon discharge, so there should be
25 some -- and they are across services -- they should have some

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1 idea of what it has meant this year. We are not comparing to
2 anything, we are not making any assumptions on rates, but there
3 is -- we did pull out this data.

4 (Slide)

5 And, likewise, with the ambulatory visits which,
6 of course, the physicians record, you don't see a lot of change.

7 Interestingly, that code for influenza seems to be rather steady
8 through the year, although if you pull it out with everything
9 else, we do tend to see the peaks a little bit more readily, but
10 exactly what this impact is, we need to do formal vaccination
11 studies. We really have one planned. We would like to get it
12 started, but like everyone else has been able to say, we have
13 impacts on time, money and other resources, but we do have one
14 planned for overseas at Yakota, if we can get to it.

15 (Slide)

16 If we look at all of the specimens that we did for
17 the last two years, we see some peaks in there that probably the
18 normal population doesn't see in the summer months, which can be
19 accounted for by our adenoviruses, but you get an idea that there
20 are many respiratory viruses out there. And, of course, this is
21 the problem, they all are flu-like illnesses and the civilian
22 population tends to group them all under flu and confuse the
23 situation.

24 (Slide)

25 If we take out those negatives and just look at

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1 the positives, then you really can see the impact that
2 adenoviruses had on our program, and these mainly are from
3 Lackland, from the Recruit Center. In fact, 20 percent of all
4 the specimens that we submitted were positive for adenovirus, and
5 from Lackland, the last time I figured 60 percent of their
6 samples were positive for adenovirus. And taken together,
7 influenza and adenovirus accounted for 78 percent of all the
8 respiratory pathogens that were isolated in this program.

9 (Slide)

10 If we take out adenovirus, now we're back to our
11 typical influenza curve that we're used to seeing, with the peaks
12 that are in the wintertime. This year was a relatively mild
13 season by accounts in the general population. Because we do tend
14 to -- well, because our program is worldwide, we are getting
15 specimens constantly, so we don't see the end that most other
16 places do -- we do tend to see the same peaks, though, at the
17 same time. That may change as we get more samples from South
18 America and we start looking at more summer peaks. This
19 information is now requested by the World Health Organization so
20 they can use it in their September meeting for the Southern
21 Hemisphere vaccine information that they will decide on for that
22 particular vaccine.

23 (Slide)

24 If we look back on some of the summary, what we've
25 been able to accomplish for the last two years since I was here,

1 up until this year it has been predominately an H3N2 year. It
2 was A-Sydney, it grew very well. It was easily manufactured.

3 Last year, we were able to isolate A-Panama. This
4 was able to cover the A-Moscow strain that had been identified as
5 an H3 variant, but it didn't grow at all. A-Panama grew, that
6 was the good news. The bad news was it didn't grow very well,
7 and that was one of the reasons for the supply problems with the
8 vaccine this year. They do have that up and running, and they
9 expect it to be okay for next year. They have production for
10 that.

11 Our molecular Department has greatly increased.
12 We do sequence analysis as well as PCR for type detection for the
13 various strains. All of this information is shared with the CDC
14 in a way that we're trying to maximize resources so that we're
15 not duplicating each other's work, but we can benefit. We do
16 have some publications in the works between the two
17 organizations.

18 This year has been predominately an H1 year. CDC
19 reports that 96 percent of their As were H1. Actually, only
20 about 64 percent of ours were H1, but that truly is a reason for
21 geography because from Korea and trailing them through the
22 Pacific, we got several H3N2s. When I reported this at the
23 VERPAC meeting in January, immediately afterwards they asked for
24 those isolates, which we'd already sent to them.

25 So, the H3s that they will analyze for next year

1 were very important to them. And we did, just last week, we got
2 another H3 from Padina.

3 We have also molecular characterization of over 50
4 of these strains and 8 have now been sent to the GenBank database
5 system -- this is from our publication so that any future
6 publications we will have to be recognized for these various
7 isolates.

8 We continue to build on the infrastructure for
9 this program. The A-Panama came about because CDC contacted us
10 in the summer that they had reports of an outbreak in Panama, but
11 they had no isolates, was there any way we could get some.

12 Howard Air Force Base was still here, but it was
13 in the process of being closed. They were literally within weeks
14 of closing. I was told when I called the Lab Officer, he didn't
15 even know if they had people available, but we stressed the
16 importance of the program, and he had collection materials.
17 Within two weeks, they had sent us 24 samples. We had isolated 9
18 Influenza-A and sent those off to CDC, and the A-Panama was
19 identified as the variant that matched the A-Moscow already
20 identified.

21 Because ours are tissue-grown isolates, they asked
22 for the original sample, which we save, and that then they could
23 use for their vaccine seed strain virus.

24 I don't have this year to say that we're going to
25 have next year's vaccine. We will still have the A-Panama, the

1 New Caledonia are still in the next year's vaccine, the B will
2 change to be Seschuan, Yamanishi virus has been around for
3 several for several years, not covered quite as well this year,
4 and the Seschuan, there are one of possible three seed viruses
5 that will cover that one. Those did not come from our lab, but
6 still the numbers that we have are impressive. They coordinate
7 with other people, these vaccine decisions have to be made very
8 early. It's a dicey situation to decide in January what should
9 be in the vaccine that we're going to take the next fall, so our
10 numbers do lend credence to what they have, and the program is
11 gaining support and even notoriety as we go forward.

12 Are there any questions?

13 DR. LaFORCE: Thank you. Bill?

14 DR. BERG: That's very useful. I am curious,
15 though, why you feel that the earlier surveillance accounts for
16 your different proportion of B virus isolates from the CDC guide,
17 and I'm wondering whether this might be due to different
18 geographic areas for your sampling. Did you look at the virus
19 isolates by geographic area, and what do you think you would find
20 if you excluded the foreign isolates and compared your U.S.
21 isolates with the CDC's U.S. isolates, whether you might end up
22 having comparable percentages of B and A?

23 MS. CANAS: I know that the H3s were a matter of
24 geography. The Bs, they stayed pretty similar for the United
25 States. I mean, we had a lot of Bs at Elmandorf and Shepherd, and

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1 they sent us a lot of samples, so it could be the geography of
2 those -- and Travis -- those particular sites sending us a lot
3 that increased our proportion. And, overall, the results are
4 probably not significantly different. It was a very unusual A-B
5 year, but there is always the artifact of surveillance that is
6 going to impact that.

7 DR. BERG: I would suggest analyzing the data by
8 geographic area and the excluding your foreign isolates,
9 comparing just your U.S. isolates with the CDC U.S. isolates, and
10 see whether you have comparable patterns then.

11 DR. HERBOLD: Does the DoD have a policy on
12 immunizing the military people. Based on the numbers here, it
13 looks like there was a lot of influenza that would be
14 preventable.

15 MS. CANAS: All active duty individuals are
16 supposed to be immunized, and I believe we claim about a 90
17 percent rate. This year, of course, there were some problems
18 with the vaccine coming in later, and I'm not real sure when --
19 Col. Diniega, do you have information on that?

20 COL. DINIEGA: Well, yes. Influenza is certainly
21 one of the universal vaccines required for the military
22 personnel, as is hepatitis-A and anthrax. But the numbers you
23 see are not only from active duty people, the requirement for
24 active duty people. You are seeing a mixture of family members,
25 I think are in the sample, and retirees.

1 MS. CANAS: And we are always trying to pull out
2 that data. It's hard to pull out that data and get good rates on
3 what that means, but we're working on that. We actually have
4 people who are trying to find that, that's why we need a vaccine
5 effectiveness study where we're actually looking -- we can
6 actually track those people who have been vaccinated, when they
7 were vaccinated versus when they came down with illness, with a
8 case controlled study. We know it's not a perfect vaccine, but
9 the statistics are impressive on how effective it is. And in an
10 immunologically healthy population, which is what we're talking
11 about, it should be about 90 percent effective.

12 In the April 20th MMWR standard that CDC put out
13 on their influenza vaccine, they have a study this year for the
14 first time on the economic impact. It would be interesting if we
15 could apply that, too, the influenza vaccine in the general
16 population could make a huge difference. We do test anybody. We
17 are looking to know how many breakthroughs there are in the
18 vaccine. Certainly, we get dependents -- and in our remote
19 sites, that's the local population.

20 DR. LaFORCE: Correct me if I'm wrong, though, but
21 last year in the military there was very little influenza, right,
22 in the active -- I mean, it looked like the match was very good,
23 and there wasn't very much disease at all, right?

24 COL. BRADSHAW: I think even across the country,
25 it was less than usual.

1 DR. LaFORCE: Right. And I am, again, still
2 struck with this huge fraction of isolates that's adenovirus. If
3 and when the adenovirus vaccine comes, you're out of business.

4 MS. CANAS: Oh, no.

5 DR. LaFORCE: No, I'm just kidding.

6 COL. MICHAEL: Rodney Michael, from the Military
7 Infectious Diseases Research Program. I have a couple of
8 questions. One, you indicated that there is growing support for
9 the surveillance program, the influenza surveillance program and
10 the work that you do, which looks pretty good. I'm wondering,
11 does that support come from Health Affairs in the form of funding
12 the development and maintenance of infrastructure especially at
13 the overseas labs. In Peru and Athens, for instance, is that
14 infrastructure fully burdened for the cost of the surveillance,
15 or where are those dollars coming from? Is Health Affairs
16 actively supporting that?

17 Then the second question goes to -- Dr. LaForce
18 just mentioned, what were the subtypes of those adenovirus
19 isolates?

20 MS. CANAS: Yes, we have good support. This was
21 an Air Force program, but it's now funded under Global Emerging
22 Infectious -- the GEIS office. They are fully supporting us. We
23 are trying to work it out. Air Force is the lead agent. We are
24 trying to work that out. But at this point in time, GEIS is
25 funding it.

1 We do the laboratory work, we are funded for that.

2 The AFRAM, NAMRIID, those are funded at those places. They pay
3 for the shipping of the specimens. We send them supplies. They
4 take care of getting the specimens to us. At this point, we are
5 -- it is fully funded. We have a lot of support.

6 Adenoviruses, we've been concentrating on getting
7 the flu subtypes. Those that we have done so far have been
8 mainly 4, but we have some 7s, but they are still in the vaccine
9 types.

10 COL. PATRICK: When you say they pay for it --

11 MS. CANAS: GEIS.

12 COL. PATRICK: GEIS pays for NMRC and AFRAMS
13 infrastructure, shipping costs and all that?

14 MS. CANAS: They support those programs -- we have
15 our influenza program that is supported in Influenza, and then
16 Influenza is supported under the NAMRIID and AFRAMS programs. Do
17 you have anything to add to that, Dr. Gaydos?

18 DR. GAYDOS: No. They put in their budget every
19 year to GEIS, and they include the influenza part of it in there,
20 and they are funded.

21 DR. LaFORCE: Yes?

22 DR. SHOPE: Bob Shope, University of Texas Medical
23 Branch. Looks like you have a lot of negatives. I suspect
24 that's common, and I'm wondering, is the Defense Department doing
25 anything to find out what those negatives are?

1 MS. CANAS: That's always a question. We always
2 wonder, did they take the specimen too late, did they not handle
3 it right, is there another virus there that we're not picking up
4 -- that's always a question. Interestingly, though, across the
5 years, the percentage negatives remains fairly constant.

6 DR. SHOPE: It's also seasonal, apparently.

7 Next slide, please.

8 MS. CANAS: Yes.

9 DR. LaFORCE: You haven't answered his question.

10 MS. CANAS: Because I lost track of what I was
11 saying.

12 DR. SHOPE: What is being done to further study
13 those negatives?

14 MS. CANAS: Well, in the laboratory, we're always
15 looking to improve what we're doing, just better techniques, we
16 try new systems. I will say one of the things we did this year,
17 just before the VERVAC meeting, the vaccines meeting in January,
18 the week before we received a shipment from Nepal and Thailand.
19 In an effort to take some information to them, the molecular
20 biologists went into the direct specimen. He chose a subpart of
21 those samples and used PCR analysis for Influenza-A and B, and
22 actually identified several that we were able to report. So,
23 those were directly from the samples, which holds promise, and
24 they did when we did the laboratory later, but this kind of
25 technology where we may not have to have a viable virus to -- of

1 course, we have to know what we're looking for. We're always
2 looking to improve that, every laboratory. But our negatives
3 are consistent with other programs and their negatives. I think
4 it's just part inherent in a program. A person may be ill, but
5 if they are no longer shedding viable virus when they take the
6 sample, we're not going to get it. If they don't handle it
7 properly, they are labile, we're not going to get it.

8 I think it's amazing that we get as many as we do,
9 especially from these overseas sites.

10 DR. SHOPE: My questions wasn't intended to be a
11 criticism.

12 MS. CANAS: Right, but you're right. This is
13 always something we're looking at -- should we be getting more
14 from these?

15 DR. LaFORCE: Col. Diniega.

16 COL. DINIEGA: Actually, at the VERVAC back in
17 February, a lot -- that same question came up because a lot of
18 the labs will look just for influenza. And the question came up,
19 why aren't we looking for other things? And I have to say that
20 what they look for are currently what we think are the important
21 things in respiratory illnesses. But I think the same question
22 goes to other reference laboratories in respiratory illness, what
23 are they looking for, and some of them are a lot more limited
24 than what the Air Force labs are.

25 MS. CANAS: Another possible part of this is the

1 rhinovirus probably makes up a part of that, and our laboratory
2 protocol is not set up to isolate the rhinovirus.

3 DR. LaFORCE: Yes, Jim?

4 LtCOL. NEVILLE: This program is dependent on
5 clinicians and all the different clinics just gathering what they
6 can. It's not that research assistants are trained to do
7 whatever, and they are not a study population where the person
8 comes in within the first 48 hours and so on. So, a lot of the
9 samples that we'll get will be negative just because of that
10 methodology.

11 But the other thing is, as Linda just said, there
12 are other pathogens that could be detected probably in that
13 specimen, but that would take a lot more laboratory resources to
14 try to ferret those out like the rhinovirus, and just that list
15 that we use is the one that we test for.

16 DR. LaFORCE: David, then Joel.

17 DR. ATKINS: Is there a clinical case definition
18 that is supposed to precipitate the sampling?

19 MS. CANAS: Yes, it is. It's very much like the
20 CDC -- fever, 101.5 greater than or equal to, cough or sore
21 throat, indication of respiratory illness.

22 DR. LaFORCE: Joel.

23 DR. GAYDOS: Joel Gaydos, Department of Defense,
24 Emerging Infections. I think there are two points in answering
25 Dr. Shope's question. One is that we certainly believe that in

1 addition to the problems with isolating the viruses and other
2 possible viruses, that we have bacterial agents out there that we
3 are not identifying. We have data that have been collected by
4 the Navy Health Research Center in San Diego, to indicate that we
5 are probably seeing a lot of microplasma, chlamydia, pneumonia,
6 and pertussis. We don't have laboratory techniques in place. We
7 aren't looking for that. So, the people in San Diego have been
8 attempting to develop that laboratory expertise, and we hope to
9 be exporting that.

10 The other thing is that these specimens are coming
11 great distances. They are being shipped on ice. We have had a
12 lot of problems with them. We do have a case definition. We do
13 try to get specimens early in the course of the clinical illness.

14 Those things aren't always working. And so we're hoping to
15 improve our collection techniques going to molecular methods
16 which will make it cheaper for us and easier for people to
17 collect them and ship them. And we started a pilot program with
18 NRHC in San Diego, and Dr. Tom Emburger at the AFIP, to look at -
19 - to compare some molecular collection techniques with our
20 current traditional techniques. So, we are trying to look at all
21 the variables that we think are important, that we're not
22 accounting for right now.

23 DR. PATRICK: This may follow-up a little bit on
24 what Joel just talked about. I notice one of the impressive
25 things in the slides is the numbers of cases of hospitalizations

1 due to pneumonia. What is the etiology of the pneumonia cases?

2 LtCOL. NEVILLE: That was just a smattering of ICD
3 codes that see in pneumonia, that whole category, 487. So we
4 didn't break up that. We could get that, but that all depends on
5 the ICD coding at the discharge diagnoses. A lot of those didn't
6 have bacteriologic confirmation of that etiology, and some of
7 those even had the etiology coded out, but in the record, the
8 medical record, there wasn't any pathology or microbiology
9 specimen to support that. So, whether there was a clinical
10 diagnosis of a pathogen or not, so that's a harder question to
11 answer without a formal study.

12 DR. PATRICK: But it seems like that might be an
13 important question to begin to try to answer, to look for sort of
14 new patterns or whatnot. I'm sure you're curious about that,
15 this is quite a few hospitalizations.

16 LtCOL. NEVILLE: The question came up about
17 vaccine failures, I thought, at one point. That's another thing
18 this program isn't designed to detect, but two years ago, of
19 those specimens that were causes of influenza, just over 180 of
20 them occurred in active duty people who had received the vaccine
21 at least two weeks before that. That means there are vaccine
22 failures, and why the vaccine didn't work for them -- no vaccine
23 is 100 percent, certainly, but that seemed like a fair number of,
24 with the number of cases that we saw.

25 DR. LaFORCE: Except that, remember, there's a

1 mathematical relationship. The higher your vaccine coverage, the
2 higher the fraction of cases that do develop the disease have
3 been vaccinated. And so the "vaccine failure" rate works out
4 with a vaccine efficacy of 90-95 percent. Once you have coverage
5 that's above that, almost every single case that you find has
6 been vaccinated. They are all vaccine failures. So, you really
7 shouldn't be too worried about that. Again, it's the population
8 based effect, and you have a powerful example of public health in
9 this, I think, the Influenza Program within the Armed Forces,
10 really.

11 I think from the Board's standpoint, we want to
12 say thank you again. We said thank you a couple of years ago,
13 thank you again. This really is very, very useful information
14 and continues to serve as, frankly, pressure to maintain the
15 important issue of surveillance for respiratory diseases, which
16 is very important. Thank you.

17 We'll finish this morning's session in terms of
18 Vaccine Health Center Work Group, a presentation by Col. Renata
19 Engler. Apparently John Grabenstein was also going to be a
20 presenter, but he's testifying in Texas, I think.

21 COL. ENGLER: That is correct.

22 DR. LaFORCE: That is correct.

23 COL. ENGLER: He was held over. The trial
24 continues.

25 DR. LaFORCE: Well, when you see John, please tell

1 him that we missed him.

2 COL. ENGLER: I will be happy to do that. I
3 understand he had the benefit of giving you the core briefing
4 about the Vaccine Healthcare Center. If you stumble on the name,
5 the pneumonic we're trying to propose is VHC. He gave you the
6 history and the background and the congressional intent of this
7 initiative as a collaboration between the Center for Disease
8 Control and the Department of Defense, and in response to a lot
9 of the concerns that have been raised in the innumerable
10 congressional hearings that have surrounded not just vaccine
11 safety, but also specifically anthrax, and for those of you, if
12 you weren't in Hawaii and didn't have a copy of the two-page
13 information paper that John and I put together, with the mission
14 vision, the congressional citation, et cetera, I did bring some
15 extra copies, but I assumed the majority had had those questions
16 answered, and unlike my usual talks, I'm going to keep this very
17 short and just have a few slides because we really want to have a
18 lot of time to discuss and have input from you all in response to
19 this being really a request for help and a request for a
20 participation and engagement of the AFEB as has been made to the
21 ACIP in the context of this network development.

22 (Slide)

23 Just to refresh your memory, this a summary of the
24 goals that after a year of hashing out between CDC and ourselves,
25 came or were extracted partly to support the fact that we are in

1 compliance with the congressional intent -- that is to enhance
2 safety and quality of vaccine delivery, the clinical site of the
3 immunization challenge, and to improve the reporting of adverse
4 events after vaccination, with the target initially being
5 anthrax, but really towards all immunization adverse events, and
6 to make the quality of those VAERS of a better depth and, in
7 addition, that the focus of the VHC network would really be to do
8 something relatively new in the context of VAERS, which is to do
9 follow-up VAERS on individuals who have had VAERS files because,
10 at the present time, in the congressional hearings, there is not
11 really good data on the outcomes of individuals who have had an
12 adverse event report, what is their quality of life, what are
13 their problems a year or two later, and the VHC resource and
14 staffing potentially has the capability to partner with local
15 facilities and health care providers to do this and to do an
16 outreach program, to really do significant quality improvement in
17 the VAERS process similar to enhance proactive safety
18 surveillance that we see in the airline industry.

19 Also, what grew out of the congressional hearings
20 was a great concern about the handling of individuals with
21 complex or multi-system adverse events. Very reminiscent of our
22 other challenges with Gulf War illness, Agent Orange, et cetera,
23 when patients in our very downsized health care system with
24 shrinking resources are complex and do not have easy, simple
25 diagnoses or have very challenging both diagnostic and management

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1 demands, the system frequently breaks down. And this is
2 increasingly also evident on the Reserve side of the house where
3 access to facilities that really had no involvement in the
4 briefings about anthrax adverse events or the clinical
5 guidelines, and it's amazing to me that it is only in the last
6 couple of months surrounding a very controversial, that it became
7 clear to us that the Sue Bailey memo that enabled individuals to
8 access health care in our DoD system even if they were not
9 drilling on active duty, if it was a vaccine-related adverse
10 event, that information never got to the VA.

11 And so in those areas where the primary access of
12 Reservists is to the VA because there is no military MTF or
13 tricare network, basically they were refused care.

14 So, as the program has evolved in terms of trying
15 to manage the predictable 1 or 2 percent of individuals who may
16 have problems with any prescription drug or vaccine, we've
17 uncovered some of the problems in our health care system and its
18 weakness and how we have to assure that our service members have
19 access to care when they do have problems because, clearly, that
20 is the passion of individuals who have not been handled well, has
21 driven a lot of congressional concern and adverse publicity for
22 anthrax and for immunizations in general. So, that's one of the
23 major focuses that led to the support for the VHC concept, as
24 also a clinical service and support, which is really a novel
25 partnership. The CDC has never been in the business of

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1 partnering on quality improvement in clinical services, and there
2 clearly are growing pains in that area.

3 In addition, the enhancement of education and
4 improved vaccine acceptability both among providers and
5 beneficiaries is an important core goal, and I think recently
6 there was very interesting article about influenza vaccine
7 acceptability among health care providers, and among the worst
8 users in civilian hospitals and least acceptability and faith in
9 vaccines were physicians and nurses. So, all of that also
10 impacts and has certainly been a factor in the anthrax program as
11 well. And then the network as a resource that shares information
12 both with the CDC and the military surveillance systems and other
13 agencies in relation to vaccine safety surveillance.

14 (Slide)

15 This is the organizational chart. John wanted,
16 when we talked about planning this request, wanted to just
17 refresh folks' memory in terms of the preliminary design and,
18 really, the VHC network is a work-in-progress, and when we
19 envisioned it, we saw the need for a clinical advisory board or
20 working group.

21 John has already been to the ACIP on this behalf,
22 and has buy-in from select members of that group to participate
23 in the VHC Clinical Advisory Board, and this is our formal
24 request to the AFEB to also submit participants in this process.

25 The group on the left, the Multidisciplinary

1 Stakeholder Clinical Working Group, which is something that we
2 all have begged for and like using draft vaccine information
3 sheets so we don't have to wait eight months after a vaccine is
4 on the street to get something to work with, to deal with some of
5 the practical clinical problem-solving that has arisen in the
6 context of immunization health care are still among the goals
7 and, at the present time, first, the Walter Reed Vaccine
8 Healthcare Center has hired 90 percent of the personnel. We have
9 just completed a nine-week training session for the nurse-
10 practitioners and the staff, and are developing SOPs, and every
11 day encountering new questions that we hadn't anticipated in the
12 logistics of this kind of a collaborative effort.

13 We see the purpose of the Clinical Advisory Board
14 as one for consultation, review, and to comment on certain Catch-
15 22 clinical management issues as well as hopefully ones that are
16 a little less shade of gray. On the development and oversight of
17 certain quality assurance protocols and the management of complex
18 adverse reactions, we are increasingly also coming up with this
19 issue of disability just as the childhood immunization adverse
20 events that were rare but disabling in terms of assuring that
21 there is adequacy of support both healthcare access and
22 disability support, if the outcome is prolonged in its impact
23 and, again, making this approach really -- there are numerous
24 cases that we struggle with which, if presented to -- recently we
25 presented a case to a national expert who does a lot of court

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1 testimony on adverse reactions, not vaccine-specific, and the
2 case we presented was a complex one. And he said, "Well, if I
3 was asked a question, you know, is this likely that this is
4 anthrax-related, I would say no, but with the details of the
5 patient and the reproducibility of the symptoms with repetitive
6 shots, if I was asked the question from a disability perspective,
7 is the adverse event possibly related, or triggered, or
8 exacerbated by the anthrax vaccine administration, I would say
9 yes, it is possible".

10 (Slide)

11 And so, in that context, to get away from the
12 adversarial positioning that individuals who have medical
13 problems need to fight for or prove that there's causality in an
14 absolute epidemiologic sense to get access to care or disability,
15 we hope that the VHC is going to help, in partnership with
16 advisory groups, develop some guidelines that eliminate some of
17 that polarization and the problems that have fed the negative
18 perceptions of the anthrax program and immunizations in general.

19 We'd like the expertise to be broad-based for the
20 advisory group, with clinical wisdom to include nursing
21 perspective, with the thought of maturing policy, not making it
22 and, again, giving the clinical side of the house a way to work
23 issues. Policy are usually one-page documents, and Ben Withers
24 made the comment that the clinical side wants details. I would
25 say that there are an awful lot of problems when you try to

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1 execute triage of a shortage just with the flu program. The CDC
2 guidelines and DoD guidelines of prioritization for risk groups
3 basically didn't work because we didn't have enough vaccine for
4 several months. Any one of the high priority groups would have
5 exhausted local individual supplies.

6 So we had to sit down at local sites and do
7 subprioritization and, you know, having a forum in places to work
8 the finer details -- which the devil is in the details, as you
9 all know, particularly in clinical care -- I think will
10 contribute to some significant and needed quality improvement in
11 immunization health care in general.

12 John and I envisioned two to three AFEB members
13 being the committed individuals, as one proposal, and the
14 question of structure, frankly, we hope will be discussed and the
15 wisdom that's in this room will help us with that. We talked
16 about one to three times per year meetings, and those being
17 either by telephone or with alternating half-day sessions that
18 are linked to one of the already existing meetings so it's not a
19 separate kind of event, and then other approaches to be defined
20 in the discussion here.

21 (Slide)

22 These are the names of the individuals that so far
23 have been identified from the ACIP side to become involved in
24 this effort. And with that, I will basically open the forum for
25 questions and discussion, and anything you all would like.

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1 DR. LaFORCE: Col. Engler's presentation is open
2 for discussion. I would say that this represents an absolutely
3 logical continuation of something that was started almost a year
4 ago in terms of discussions. So, from the Chair's standpoint, I
5 am delighted to see that this has progressed in the way that it
6 has.

7 COL. ENGLER: I just want to say that from the
8 time last year when the CDC asked us at Walter Reed to propose a
9 plan -- we agonized about how to do this -- to address all the
10 concerns we've had for many years and that have been discussed
11 here, also about deficiencies in immunization training, et
12 cetera.

13 I think there's a huge -- I'm just really
14 delighted with the enthusiasm that we have found, and I would ask
15 all the services and all the individuals here, please, we are a
16 small group at this point. The personnel are learning, and it's
17 been a very interesting journey because, as you know, the
18 individuals that are hired are through a Federal Occupational
19 Health contract, and they are civilian, and it's been very
20 interesting.

21 We had them go through the AVIP University for a
22 week, through the five-week training that we do for enlisted
23 personnel at Walter Reed at the Triservice School, and it was
24 interesting because they brought a civilian perspective to the
25 issues and the concerns. And so to make these individuals

1 sympathetic to the military perspectives and challenges -- and,
2 of course, I don't know if any of you have noticed that the
3 publicity and the adverse articles and controversy continues to
4 foment at a fairly high rate, and every other day I have to go --
5 they say, "Look at this article. There is evidence of a cover-
6 up", and trying to explain the press to civilians who I am trying
7 to engage as a team to help work with us has really been a
8 learning journey. And we're supposed to be an outreach mediator
9 group, and we're supposed to be a safe haven.

10 One of the things I wanted to bring up because it
11 has given me gray hairs is the question of confidentiality.
12 Congress really wants this unit to enable people to file
13 confidential VAERS with help, but where the VHC, without the
14 permission of the individual, would not make that visible to
15 anyone in terms of the identity. They would just be coded and
16 sent in to the FDA system. So they would bypass the internal
17 VAERS process within the military system, and how to align that.

18
19 Now, information from FDA VAERS goes to AVIP in
20 relation to anthrax, but the logistics just to the agency data
21 connectivity, et cetera, it's very complicated and we really do
22 need a lot of help and would like places to bounce the problem
23 and the questions off of and guidance of where to go. We'll need
24 all of your help in this room for each of the services, and
25 particularly also the Reserves seems to be a growing area of

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1 challenge and problems to work through.

2 DR. LaFORCE: Dick?

3 DR. MILLER: Col. Engler, VAERS certainly reports
4 a small fraction of the true adverse events, and a particular
5 fraction there are some biases that go into it.

6 COL. ENGLER: Absolutely.

7 DR. MILLER: As you bring these health centers up
8 and continue to accrue VAERS, are you concerned that one of the
9 things that VAERS does provide, and that is the recognition of
10 trends, will be lost? In other words, the number will go up
11 every time you bring a VHC up, and the mix of reports will go up,
12 so that will be lost. Does this concern you at all?

13 COL. ENGLER: Well, let me start with what the
14 concern congressionally and nationally is. The congressional and
15 national concern is that the visibility of VAERS as a system
16 among health care providers is incredibly poor. And what's
17 already happened is, I can't tell you how many times cases now
18 come to us where a specialty is involved, we go and lecture about
19 range of adverse events and vaccines.

20 And the Chief of Neurology at Walter Reed recently
21 said, "You know, before you were making this visible and the
22 concerns, et cetera, there are cases which probably should have
23 been reported that were serious, with neurologic symptoms, but it
24 didn't dawn on anybody because nobody thought about VAERS".

25 So, frankly, the greater problem is that VAERS is

1 so -- I mean, if we have trouble with general adverse drug
2 reaction reporting, and that's a JACO-identified problem, we have
3 an even huger problem with VAERS. And so I think if the VHC
4 improves the quality of the VAERS and their system can come back
5 to the VHC staff and say, can you investigate, and can you find
6 out a year later with another diagnosis made, that will
7 compensate your concern tremendously, in that the quality and
8 ability to analyze the VAERS cases by the reviewing body should
9 be significantly improved.

10 But, you know, we in the clinical front lines are
11 continually being challenged with -- we'll see a patient who will
12 say, you know -- and I don't care if it's Air Force, Army, Navy -
13 - down at my base there are 100 other people who have problems,
14 but they are afraid to come forward. They are afraid of the
15 impact. They are afraid they won't get any disability. I have
16 no response to that, and I really would like to know the truth of
17 that claim. And that's having more negative impact on trust in
18 anthrax or any other -- you know, anthrax being now sort of the
19 sentinel or lightning rod than anything else in relation to
20 vaccines -- you know, VAERS has been recognized, yes, right now
21 if people die or are hospitalized are really severe, but we do
22 want to know about neurologic or indolent medical problems that
23 result in loss of quality of life and morbidity because it's that
24 group that's driving a lot of the press and the congressional --
25 you know, it may not kill us, it may not put us in the hospital,

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1 but you've trashed our life. We can't do what we've done before.

2 And part of what we're struggling with also now is
3 do we do an FM-36 on everybody and then -- you know, who have a
4 VAERS file through the VHC, and do follow-up, so we can come back
5 and say -- right now if a patient comes in, or an active duty
6 member, and says, "Okay, I read the little blurb on the VIF and
7 all that, but if I'm one of the rare ones that has a problem, how
8 likely am I to be okay a year later or two years later". No one
9 has that data.

10 So, I think the tradeoff of what we're trying to
11 do is far superior to -- it was never an epidemiologic system
12 anyway, it was really just to say, oh, there's a cluster, let's
13 ask some more questions.

14 DR. LaFORCE: Bill.

15 DR. BERG: Bill Berg, Hampton. As someone who
16 spent most of his Navy career dealing with vaccines, including
17 the JE vaccine study, and now deals with this as a public health
18 threat, I think this program is great. It addresses a gap that
19 has long been needed. We get increasingly detailed instructions
20 on how to give vaccines, but little on what to do with the
21 adverse reactions. So, I commend you for this.

22 I do have two questions. The Advisory Board, as
23 you contemplate it, what sort of staffing do you anticipate
24 supporting it?

25 COL. ENGLER: Well, you know, it's interesting,

1 just as we started off -- at this point in time, there's -- this
2 is a CDC, with my little department providing a huge amount of
3 unfunded, unresourced infrastructure support and some personnel
4 we're training for the front line in the outreach.

5 I am working on the faith that the CDC, which
6 controls the budget and has the National Immunization Program
7 Office, et cetera, will be the coordinator for the Board and will
8 provide the resources for the Board. They have not detailed that
9 out for me, but I'd be delighted to have your input as to what
10 questions should be asked so that we can pass it on to the CDC.

11 DR. BERG: Well, I think as a minimum, if this
12 Advisory Panel is going to be productive, there should be a staff
13 who pulls together the information, writes up the issues, writes
14 up questions, and then gives them to the panel ahead of time to
15 at least be able to contemplate it. It's not going to be very
16 effective if people walk in cold and the question is -- you know,
17 and I think it would be preparation for the AFEB to serve as sort
18 of a model for this.

19 COL. ENGLER: I mean, it was always anticipated as
20 such because one of the things that we're having a little trouble
21 with is that there is in the congressional language this thing
22 about -- they want access to the VHC and no barriers to access,
23 but they also say they want somebody to decide what patients can
24 come to the VHC, which makes no sense.

25 And so I've explained that these types of words --

1 you know, you're bringing issues, generic problems, or groups of
2 patients, and you're trying to decide on a strategy. I mean, I
3 think that's -- what you just said is well understood. The
4 support for doing it has yet to be defined. And at the present
5 time, not one cent, except for the work that I and my department
6 do and Walter Reed provides in terms of space, et cetera, there's
7 not one penny on the DoD side. So, it's all money that's routed
8 through the NIP, the National Immunization Program Office of the
9 Center for Disease Control.

10 There is discussion about a partnering if this is
11 going to become a core function in the future that there needs to
12 be a parallel partnership both in finances as well as -- you
13 know, and that there needs to be some DoD line item funding, and
14 that is under discussion, and there is a proposal in MGen. West's
15 office to the congressional budgeting.

16 DR. LaFORCE: Rosie?

17 DR. SOKAS: I had two comments. One is, I think
18 the generic idea -- well, the actual idea of a nurturing,
19 nonthreatening, supported environment for this is fabulous, that
20 it's very interesting from a health services research perspective
21 and may actually parallel -- I mean, the hope would be that it
22 would parallel some of the studies in occupational health where
23 if you stop fighting the claims, you wind up with earlier
24 recognition, lots of, you know, things that you ordinarily
25 wouldn't catch, but then the cost per case goes way down because

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1 you have fewer people going out on permanent disability and all
2 the other attendant outcomes of a hostile system.

3 The question I have is a purely bureaucratic one.

4 My understanding is that in order to facilitate and get this
5 moving, instead of creating a separate FACA, such as AFEB and
6 AFIP, that you've got a working group together that then will
7 actually be able to get this work done, but because of FACA -- I
8 mean, the actual approval for the work is going to have to -- I'm
9 assuming it's going to have to come back through AFEB. And I'm
10 just wondering --

11 COL. ENGLER: Well, I think that John, when we
12 were talking advisory group -- because there's work that goes on
13 between the CDC group and us and the VHC staff continually. So,
14 before things would come to the Advisory Board, it's not like,
15 you know, every little item comes to the Advisory Board, would be
16 -- they would have already been worked, hashed, staffed and, you
17 know, what we plan is also to get sort of a multi-service -- and
18 Adm. Clinton has asked that even though we're not chartered for
19 that, to already reach out to the VA, so that things that -- it's
20 really the points of -- not the minutia, but the areas of gray,
21 the difficult, the tough stuff, that would be brought to the
22 Advisory Group, and then with recommendations, and then it would
23 go back.

24 Where the senior part of that evolves and is
25 structuring still remains to be defined.

1 DR. SOKAS: And the interesting question there is,
2 you've got two advisory groups and two federally constituted
3 advisory groups, or more perhaps, that ultimately you'll be
4 bringing it back to, so it's just kind of an interesting and, I
5 think, uncharted territory in a way.

6 COL. ENGLER: Well, this marriage is uncharted,
7 I mean, in terms of CDC and a clinical mission.

8 LtCOL. RIDDLE: John actually might be able to
9 comment on this because the way I understand the rules with FACA,
10 as long as we hold a working group for discussions for
11 formulation of recommendations for a federal advisory committee,
12 those working groups won't fall under the rules as far as open
13 committees, Federal Register, all of those kind of things, but a
14 group that would make the formal recommendation probably would.
15 John, are you -- Mr. Casper?

16 MR. CASPER: I really can't comment.

17 LtCOL. RIDDLE: We would have to work that through
18 with Army Committee Management.

19 DR. SOKAS: So the working group would have to be
20 a working group, not an advisory group, I guess.

21 MR. CASPER: Right, if it's composed of
22 nongovernment members, it becomes a FACA situation.

23 COL. ENGLER: One of the things we needed is a
24 forum where you could work stuff that wasn't a public forum.

25 DR. ALEXANDER: You know, under contract with NIP

1 of CDC, we operate the National Immunization Hotline. And one of
2 the things that we've learned in handling these gazillions of
3 calls each year is that there's tremendous confusion in the
4 public sector about immunizations in general, and no matter how
5 you proceed with this, I would really encourage you to actively
6 consider the public education requirements as an integral
7 component and really providing an interface with the public as
8 questions arise because some of the frustration that we hear from
9 callers is that it took them a long time to find out there's
10 someplace where they can ventilate, and in the course of that
11 time, their anger builds and their attitude changes. Where they
12 start out as initially being just curious and perhaps concerned,
13 by the time they are bounced around, they end up being angry and
14 frustrated, and they get in that litigious mindset which is hard
15 to readjust.

16 The other suggestion, just in terms of advisory
17 group makeup, as difficult as it is to work with public
18 constituents sometimes, it's really important that they be part
19 of the process and they be included in whatever media events are
20 associated with it because they can deflect and diffuse a lot of
21 confusion.

22 COL. ENGLER: One of the things that -- part of
23 the difficulties that the AVIP, which has a lot of resources
24 developed for education and in answering questions, is not a
25 clinical group. And, similarly, the CDC actually has welcomed

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1 the idea that if there is an adverse event management or
2 strategy, that there's a place that they can route that. We
3 can't, and we're not resourced to take over a massive mission
4 like AVIP, but that really we become the other bookend for the
5 clinical piece. And we've had a couple of cases already where a
6 provided in the civilian sector called CDC about an adverse event
7 issue, and whoever they talked to at the CDC said, "Oh, there's
8 no problem". And then the provider told the patient, "Go home
9 until you get sicker", and eventually -- we are now getting
10 referrals actually via majorbase.com, and then Dr. Nash, who
11 knows we try to manage the patients with no bias, et cetera. So,
12 it would be nice if we didn't have to get people to go through
13 that route to get to us.

14 And one of the things for the advisory group is,
15 there's a huge need for expanded fact sheets. So, Tom Waites, at
16 Bioport, I said, "Look, there's been so much hoopla about what
17 your factory has gone through, help us write a fact sheet that
18 sort of gives some of the history and the fact that all
19 manufacturing practices have required revamps of factories, and
20 what's fact or fiction, and on that fact sheet maybe link to you
21 directly because I don't particularly want my staff to have to
22 learn about what the minutia issues are at Bioport plant or
23 whatever". So, we're finding every day that there are these
24 holes, and you're absolutely right, as we send the nurse-
25 practitioners out to individual immunization sites and MTFs and

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1 do educational outreach, one of the things we're asking people is
2 "what do you need? What at the clinical front lines haven't you
3 got that, in terms of the AVIP generic messaging, doesn't answer
4 the mail at the clinical front lines". So, that is definitely
5 dominant in the goal and, if anything, the education piece, the
6 school, the standardization of training issues, and I think John
7 briefed you all -- I had put that slide in on the MMWR in March
8 2000 -- which gives us the first published guidelines for minimum
9 standards for quality immunizations in nontraditional sites for
10 adults. That's going to be a JACO standard. So, one of the
11 things we need to do is find out what's it going to take to help
12 people in the individual immunization sites meet those standards?
13 What are the resource requirements?

14 So, we feel absolutely that we hope to be a very
15 neutral, open, nurturing kind of -- and the people we have
16 selected and hired have been on the nurturing, very nurturing
17 side, so that they are folks that people feel comfortable to talk
18 to, they feel safe, and they can let us know. And we've had a
19 couple of already angry -- we're not even open for business but,
20 you know, angry folks who -- but it takes a couple of hours to
21 sit down and work through their issues.

22 But one of the big things, too, is the disability
23 question, that people are afraid -- you know, it doesn't matter
24 if you say this happens only 1 in 10 million -- you know, if
25 people who are healthy fear that they are the one, and then when

1 they are sick the system abandons them or doesn't provide them a
2 reasonable way to survive, that's really a lot of what has driven
3 the terror about the vaccine that may -- you know, and John says,
4 well, look at the data. I said, "Well, John, if data solved the
5 problem, we've put data out the whazoo". It's a human issue of
6 fear and quality of life, and the roulette wheel of 'what if I'm
7 the person', and, clearly, there are people who we can't explain
8 and who have some pretty morbid problems that are generally
9 associated and that are reproducible in terms of several doses,
10 and we need to be honest about looking at those folks and making
11 sure that they're taken care of and that they are made visible to
12 the system.

13 DR. LaFORCE: Let's close this morning's session.

14 What I'd like to do is read from the Army Surgeon General, the
15 actual request, and I refer you to paragraph 2.

16 "To support the VHC Network, I request the AFEB
17 appoint two or three members to collaborate with the CDC's
18 Advisory Committee on Immunization Practices, forming a VHC
19 Advisory Board. The ACIP has already named its members to this
20 Board.

21 "This Board will consult, review, and comment on
22 clinical management issues, protocols, and other vaccine delivery
23 issues to the VHC Network, conferring up to three times per year.

24 The members of this Board will report back to their full
25 committees, as appropriate.

1 "Request the AFEB provide: a) names of two to
2 three members to serve on this working group; b) recommendations
3 on settings in which to confer with VHC leadership, i.e.,
4 teleconferences, alternating sessions at ACIP and AFEB meetings."

5 So, Board members, please reflect on this because
6 we're going to have to come back and discuss this. I will say
7 that while I was on the ACIP -- this was several years ago now,
8 about 10-15 years ago -- during the pertussis difficulties -- and
9 those of you who lived through the pertussis difficulties at that
10 time, boy, that was hard -- I mean, to go to ACIP meetings and,
11 again, it was mothers who were concerned with this, and it was
12 just extraordinarily difficult to work through -- and it turned
13 out that the solution for all of this was the establishment of
14 the Childhood Vaccine Injury Process, which once and for all --
15 at first, when I heard about this and on ACIP discussing this, I
16 really wasn't very enthused about this. But then as we started
17 thinking about it, what it did is it codified a series of
18 clinical conditions that basically were determined as sort of no-
19 fault. If you had received the vaccine and you fell into that
20 particular category, there was no longer a need to litigate that.

21 And when it all sort of got played out, it took, Dick, probably
22 what, a year or two years to get it rolling. But once it rolled
23 out, the costs per case plummeted. The number of -- I won't say
24 complaints, or the number of cases that came up annually
25 plummeted. It didn't go up, it fell. And that whole process now

1 has generated such a surplus of funds that they are trying to
2 figure out what to do with this surplus of funds that were set
3 aside to actually pay for these injuries.

4 So, the lesson that I learned out of all this is,
5 gee whiz, thinking about the problem in terms of turning it 180
6 degrees, which is what Renata is suggesting, in point of fact,
7 was not only a good idea, it was a terrific idea in terms of
8 trying to deal with that problem. That's all.

9 Okay. Let's break for lunch, and could we meet
10 back at 1:15. Thank you.

11 (Whereupon, at 12:00 noon, the luncheon recess was
12 taken.)

13
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19
20 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

21 (1:20 p.m.)

22 DR. LaFORCE: Let's get started. Just a couple of
23 housekeeping announcements. This evening, we'll meet -- for
24 those of you who are going to the crabhouse, we'll meet at 6:30,
25 or 1830, in the lobby, and we'll take the photograph that we were

1 to take today, we'll do that tomorrow. So, when we finish today,
2 if you're not taking the tour, you are free to do whatever you
3 wish, and those that are going to dinner will meet at 6:30 in the
4 lobby.

5 This afternoon, we really have a linked series of
6 presentations on military requirements -- or the question about
7 military requirements for HIV vaccine, and the presentation of
8 the question will be given by LtCol. Scott.

9 I'm sorry, before we go any further, greetings to
10 Gen. Parker.

11 MGEN. PARKER: Thank you for all your fine work,
12 appreciate you every day.

13 LtCOL. SCOTT: Sirs, thank you very much. On
14 behalf of Col. John Ball and Gen. Kiley, we're grateful for the
15 opportunity to bring this question to you so that you can provide
16 us with some insight in finding the way ahead in what has been of
17 moderate difficulty for us.

18 My name is Brian Scott. I'm an Occupational
19 Medicine physician. I'm assigned as a Combat Developer, which
20 means I write user requirements documents as part of what I do.

21 (Slide)

22 We have brought this question to you because the
23 problem for us at our end was not cut and dried. And so the
24 Director of Combat and Doctrine Development, at the Army Medical
25 Department Center and School, has asked you this question: We

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1 would like some serious professional insight on how to go forward
2 in establishing how good an HIV vaccine should be. How should
3 we use an HIV vaccine? We would like your recommendations to
4 help us.

5 You are going to receive some information
6 following my brief presentation of the question, from the people
7 who are most immersed in the science and in the development of
8 HIV vaccine, but I'm going to talk to you from the perspective of
9 the bureaucrat who has to type on the piece of paper.

10 (Slide)

11 You are going to hear from the researchers about
12 their research, and it's been ongoing since '86 or before. And
13 because of a targeted reprogramming of some money to perform
14 advanced development of an HIV vaccine, it became incumbent upon
15 my command to obey the DoD acquisition system and pen a
16 requirements document that talks about a vaccine, and this
17 Operational Requirements Document is an instrument of art and has
18 a certain set of contents that brings us here to you.

19 (Slide)

20 We have to talk about the utility and the use of
21 the candidate solution -- the vaccine would be a solution in this
22 case -- and we have to outline performance and capabilities.
23 It's not as specific as a MIL spec -- the vial will be this many
24 millimeters -- but we have to talk about the performance
25 characteristics of the candidate vaccine. We also have to

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1 establish, at least at first blush, a number to procure, which of
2 course immediately demands, well, how are you going to use it.
3 So, if I could go on from that.

4 (Slide)

5 Why then do we want to ask you so far ahead of the
6 physical availability of the product vaccine? Why do we want to
7 ask the Epidemiological Board to advise us? Because, indeed,
8 since we are dealing with a concept of a product, we can't quite
9 come to grips with how best to use it.

10 Some of the questions one could argue are almost
11 philosophical -- total force versus high risk population only, et
12 cetera. And since you are the charter body, we thought this was
13 an appropriate place to come ask the question.

14 (Slide)

15 So, in specific, what are the parameters
16 describing the performance of this vaccine with which we request
17 your assistance? Who should get it? How good should it work,
18 how well should it work? How quickly should it work? How should
19 we fit it in, the dosing schedule?

20 What you see here are performance characteristics
21 that we have written in a draft Operational Requirements
22 Document. The ones with asterisks are make or break parameters
23 for the product. We have nominated those. That has not yet been
24 approved. At our end, we have said these should be make or break
25 criteria.

1 We believe that there should be the ability to
2 discern between having been immunized with the vaccine and having
3 an infection with HIV. We believe that if not a sterilizing
4 vaccine, it should be a vaccine that aborts transmission.

5 (Slide)

6 Other parameters not so difficult to get our hands
7 around are that, of course, this is intended to be an FDA-
8 approved biological, or pharmaceutical perhaps, and time to
9 protection we believe is acceptably described, as well as
10 duration of protection and shelf life.

11 (Slide)

12 And so we are asking you to discuss these four
13 things.

14 The effectiveness of the vaccine and its efficacy
15 in use.

16 Please discuss for us and make a recommendation
17 about sterilization and transmission.

18 If you would make a recommendation to us about
19 discerning between the vaccinated and the infected.

20 And if you would, importantly, talk to us about
21 how best to approach target populations. In other words, how
22 good should a vaccine be as far as generating the intended immune
23 response? Given that, how good should the vaccine be in
24 protecting against an infectious pressure?

25 (Slide)

1 Can we employ, should we employ, what is your
2 recommendation about a vaccine, if we do not also expect it to
3 abort transmission? I'm not saying that that's being proposed,
4 but we would like a recommendation on that specific point.

5 (Slide)

6 In case it is not a sterilizing vaccine, what
7 might you recommend to us about use and utility?

8 (Slide)

9 Would you recommend to us how we deal in a force
10 with the status of the immunized versus the infected vis-a-vis
11 their administrative status? And can we live with a vaccine if
12 we can't discern between the two groups?

13 (Slide)

14 Should we consider offering this vaccine to the
15 total force? What do we need to know in order to make that
16 decision? If not, what subpopulation should be targeted? If a
17 high-risk population is intended to be the target, would you make
18 a recommendation to us on how we might define that high-risk
19 population and what data we will need to seek. And then, how
20 might that vary given the other parameters we've discussed?
21 Might the vaccine only be used upon departure from the
22 Continental U.S.? And would you talk to us about how we might
23 proceed to institute the use of this vaccine across the force.

24 So, we've asked you a lot of questions, or facets
25 of a question, that deal with policy, and policy usually derives

1 from and devolves from what you know about a product you intend
2 to use. And I started by saying we don't have it yet, and yet
3 it's incumbent upon us to at least get our hands around our best
4 concept of how we will do this.

5 Now, it's always great to be the after-lunch
6 speaker. In this case, it's not too bad to be the after-lunch
7 speaker because that's my last slide.

8 So, I've brought you a very simple, banal question
9 that I think is probably worthy of chewing on because we think
10 the impact of the answer might be fairly weighty. From our end,
11 again, we are the command that is required to write the user
12 requirements in concert and in collaboration with the research
13 community and the advanced development community, not in our own
14 little hole and then mail it forward. But we believe that we can
15 best do this and, as stewards of tax dollars best do this, if you
16 will provide to us your recommendation as the recommending body.

17 Subject to your questions, that's all I've
18 brought.

19 DR. LaFORCE: Yes?

20 COL. DINIEGA: Brian, for the edification of the
21 Board, do you write the Requirements Document on behalf of all
22 the services?

23 LtCOL. SCOTT: This candidate solution was brought
24 to the Army Medical Department Center and School, and so right
25 now we are writing an Army Requirement. What happens then next -

1 - and I'll go back to whether or not it's next or simultaneous --
2 is that we then send the draft to the other services and say, are
3 you interested, and they have a couple of levels of interest they
4 can sign up to -- I'm interested, let me know, or I'm really
5 interested, here are some dollars. In reality, that happens
6 somewhat simultaneously because we're actually allowed to talk to
7 people with other colored shirts, and so we have kept our
8 colleagues in Preventive Medicine and in User Requirements
9 abreast of what we're thinking about, and so it won't be a total
10 surprise. But right now, it is an Army Requirements Document.
11 It was brought to us as a request from the Medical Materiel
12 Development Activity in this command.

13 DR. LaFORCE: Questions?

14 COL. MICHAEL: Col. Scott, maybe a simpler
15 question, has the user community -- has the user community
16 decided that it needs an HIV vaccine?

17 LtCOL. SCOTT: The user community is --

18 COL. MICHAEL: This almost seems to have been
19 generated in the scientific community and not the user community.

20 LtCOL. SCOTT: That's correct, Col. Michael. We
21 were going our merry way and the Medical Materiel Development
22 Activity said, "We have a candidate solution and a directed
23 funding innovation, please write us a Requirements Document". We
24 had not de novo asked for an HIV vaccine. So, that's true.

25 What we, as the user's representative for

1 acquisition, what we have been able to do is poll major command
2 surgeons, consultants in Infectious Disease Preventive Medicine,
3 our service counterparts, and say, what can you tell us what you
4 think about the requirements for this vaccine? Some of those
5 comments said, we don't want such a vaccine. Other comments
6 said, by gosh, what a great idea, I want two. So, some of the
7 comments were widely disparate. But it's true, it was not
8 something we "thunk" up ahead of time.

9 Our general requirements that are the iteration
10 before the specific requirement document are much more broad.
11 They say things like "protect people from infectious disease
12 threats, whether endemic or weaponized, in all venues around the
13 world" -- very, very broad statements.

14 So, a candidate HIV vaccine is certainly something
15 that would fall in that pigeonhole. So, it's not unreasonable to
16 say, we have a candidate vaccine, please write a requirements
17 document. It's a slightly unusual candidate vaccine because of
18 the impact of the disease, the impact of infection, and the
19 difficulties in administration.

20 DR. LaFORCE: Other questions, clarifications?

21 (No response.)

22 If not, fine. Let's move on to LtCol. Clayson's
23 presentation on HIV Vaccine Advanced Development.

24 COL. CLAYSON: Good afternoon, Gen. Parker, Board
25 members. I'd like to thank you for this opportunity to come and

1 address this issue with you. I am the Deputy Product Manager for
2 the Pharmaceutical Systems at the Army's Medical Materiel
3 Development Activity, and I also just happen to be the Product
4 Manager for HIV vaccines.

5 What I was going to say at this time was that Col.
6 McNeil has already given you a briefing about the military need
7 and a lot of the scientific issues related to this, and this is
8 Col. McNeil's presentation here, so we need to switch the slides,
9 but he's going to talk after me, so he will give you the briefing
10 on needs and a lot of the technical issues after my briefing.
11 I'm going to focus primarily on the programmatic issues of HIV
12 vaccine development.

13 (Slide)

14 The objective of the HIV vaccine program is to
15 develop and field an FDA-approved, shelf life stable vaccine to
16 prevent disease caused by HIV. Next slide, please.

17 (Slide)

18 What I hope to do with this slide is give you a
19 snapshot in time of where we are today, and that will put the
20 rest of the briefing in context.

21 We are currently in Acquisition Phase I. We
22 conducted a Milestone I In-Process Review, or IPR, back in
23 September of '00. At that time, all of the program documentation
24 except for the draft ORD was approved. This would include the
25 Acquisition Decision Memorandum, the Integrated Program Summary,

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1 and the Phase I Exit Criteria to allow us or permit us to go from
2 Acquisition Phase I to Acquisition Phase II. At that time, a
3 prime-boost strategy for the development of a clade E vaccine was
4 approved, and also at that time a Milestone II In-Process Review
5 was planned for the first quarter of FY02, just a few months from
6 now. Next slide, please.

7 (Slide)

8 At the Milestone I IPR, the key acquisition
9 players were identified. The Walter Reed Army Institute of
10 Research was designated as the lead laboratory. The Army's
11 Medical Materiel Development Activity was identified as the
12 materiel developer. The Army Medical Department Center and
13 School was identified as the combat developer, and the Army's
14 Medical Materiel Agency was identified as the logistician. Next
15 slide, please.

16 (Slide)

17 Col. McNeil's going to talk to you a lot about the
18 prime-boos strategy for HIV vaccines. Let me give you -- since I
19 ended up talking first, let me give you a brief discussion on
20 this.

21 The vaccine will be made up of two components, a
22 prime component and a boos component. The purpose of the prime
23 component is to induce cellular immunity to HIV. In other words,
24 the purpose is to kill virus-infected cells. The virus will
25 exist in the body in one of two forms, either inside the cell or

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1 free-floating, and the purpose of this component is to kill all
2 the cells infected with HIV. The purpose of the boost component
3 then is induce a humoral immunity to bind up all of the free HIV
4 virus in the body.

5 Prior to the Milestone I, an exhaustive market
6 investigation was conducted, and a single candidate vaccine was
7 selected as the prime component of the vaccine, and this is
8 Aventis-Pasteur's canary-pox vaccine.

9 There were three candidates that were identified
10 for further down selection as parts of a boost component. They
11 include Chiron's vaccine, Aventis-Pasteur's vaccine, and Vaxgen's
12 vaccine. And Phase II studies were planned in order to do a
13 head-to-head comparison of these three vaccines for the purpose
14 of down selection, and those Phase II trials are ongoing and are
15 nearly complete. I can tell you at this time, for a variety of
16 reasons, that Vaxgen's vaccine will be the vaccine that we
17 proceed with in our Phase III trials. Next slide, please.

18 (Slide)

19 And it is the status of the ORD that really brings
20 us here today. At the Milestone I IPR, many people in the room
21 had seen the draft ORD for the first time, and there was a lot of
22 discussion, comments, in some cases disagreement, about what the
23 parameters of the ORD should be. And so the message that went
24 home with the combat developer was we need to staff this within
25 the AMEDD and try to come up with a consensus. And in many

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1 cases, we didn't really come up with that consensus, and that's
2 what's led us here today.

3 After the AFEB meets and prepares recommendations
4 and sends that back to the combat developer, the ORD then will go
5 to worldwide staffing. It needs TRADOC approval. It also
6 requires Chief of Staff of the Army approval, and a problem for
7 the materiel developer is that this is not likely to be completed
8 by the Milestone II date of the first quarter of FY02.
9 Nevertheless, we're going to conduct a meeting in any event.
10 Next slide, please.

11 (Slide)

12 The discussions at the Milestone I IPR about the
13 ORD centered around two issues. One was what the efficacy
14 requirements should be, and the other was which parameters should
15 be defined as key performance parameters. And key performance
16 parameters are defined here by the Defense Systems Management
17 College's Glossary of Defense Acquisition Acronyms and Terms.
18 And I'm not going to read this to you, but I do want to point out
19 that these are capabilities that are so significant that failure
20 leads to one of three things -- either for the concept to be re-
21 evaluated if you are early in the program, the system to be
22 reassessed if you are early in the program, or the program could
23 be terminated if the performance parameter cannot be met.

24 So, these should be must-have performance
25 parameters -- not nice-to-have, but must-have. These are items

1 that cannot be traded. What I mean by that is as the materiel
2 developer, as we are developing along, we are managing three of
3 three things -- cost, schedule and performance. And if we run
4 into budget-overrides or if the schedule is slipping, we can
5 often trade performance in order to catch up on the schedule of
6 the cost. But a key performance parameter is those items, as
7 defined, that cannot be traded. They are must-have. Next slide,
8 please.

9 (Slide)

10 At the Milestone I IPR, these were the performance
11 parameters recommended by the combat developer, and those with
12 the red asterisks here were those -- at that time were proposed
13 by the combat developer as key performance parameters. What I
14 should say is that, if I read Col. Scott's slide correctly,
15 approval by the U.S. FDA and the efficacy has since been de-
16 selected, I guess, as key performance parameters, and that the
17 only remaining key performance parameters are dosing regimen, the
18 prevention of virus transmission, and the ability to distinguish
19 between infection and vaccinee.

20 So, these are the performance requirements.
21 Approval by the FDA -- in my opinion, it's not unreasonable to
22 include that as a key performance parameter, although there are
23 people, some in the room, that would disagree with me on that.

24 The efficacy requirement I'll talk to with the
25 next slide.

1 Dosing regiment. The threshold requirement is a
2 2-dose vaccine, and the objective is a 1-dose vaccine and, quite
3 frankly, this is a reasonable request. There are a lot of
4 problems associated with trying to give vaccines that have four,
5 five, six doses, and anthrax is a good example of that, a lot of
6 logistics tales. But there is some disagreement about whether or
7 not this should be a key performance parameter.

8 If we had a vaccine that met all of the other
9 requirements but was a 3-dose vaccine, for example, what we would
10 be telling the services is, while this vaccine is good enough for
11 everybody else, it's not good enough for the DoD. We won't buy
12 or use a 3-dose vaccine. And based on that rationale, the
13 materiel developer does not believe this should be a key
14 performance parameter.

15 Prevent virus transmission. It's really hard for
16 me to conceive of a vaccine that will prevent disease that
17 doesn't either severely reduce or completely eliminate the
18 ability to prevent virus transmission, but we haven't done that
19 test yet so we don't know where we are at this point.

20 The ability to distinguish between infection and
21 vaccinees. That's a very reasonable request. There are a lot of
22 problems medically, politically, social problems that would exit
23 if we could not distinguish between a person who is infected and
24 a person who has been vaccinated. And so keeping this as a key
25 performance parameters is -- the requirement is reasonable and

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1 having that as a key performance parameter is also reasonable.

2 And the rest of these parameters are also quite
3 reasonable, and we really don't need to belabor the point here.

4 CAPT. YUND: That last item, are you saying that
5 you have to be able to make that determination serologically
6 without access to the historical sequence of previous negative
7 tests and the date of the vaccination series?

8 LtCOL. CLAYSON: I'm glad you asked that question
9 because it reminded me to mention something that I didn't say,
10 and that was that we can do this today with the vaccine we're
11 currently proposing. We can distinguish between those
12 individuals that have been vaccinated versus those that have been
13 infected naturally. We are currently doing that in Thailand
14 today, as we speak.

15 Now, I have to say that the tests that we use are
16 relatively expensive compared to other types of tests. Col.
17 McNeil will talk during his briefing about some new tests which
18 are currently up in front of the FDA for approval and which
19 should be approved by the time that we interface three studies,
20 and will certainly be out there and available for routine
21 screening by the time we're ready to deploy this vaccine for use
22 in the military. Types of screening could be serological, and
23 others. Next slide, please.

24 (Slide)

25 I'd like to go back then to the efficacy

1 requirements in the ORD. Currently, the draft ORD, as written,
2 has a threshold requirement of 90 percent -- and I apologize that
3 you can't read this from the board, but it is there in front of
4 you on the slide. The objective is 95 percent. And the
5 rationale for using these numbers is that this is a lethal
6 disease and we want the very best vaccine that we can get for our
7 forces, and that's not an unreasonable argument.

8 What I would like to point out with this slide,
9 though -- this is a list of 18 vaccines, many of which are just
10 as deadly, or more so, than HIV, and our historical precedent
11 here is 80 percent for all the vaccines included on that list.
12 Some of these are ORD, some are JORDs, some are JSORs, but they
13 all have an 80-percent efficacy requirement, and some of these,
14 like anthrax, dengue, botulinum, are just as deadly as HIV, or
15 maybe even more so, and the requirements in the past have always
16 been 80 percent. Next slide, please.

17 (Slide)

18 At the Milestone I IPR, exit criteria were
19 approved. These are exit criteria to permit us to going from
20 Acquisition Phase I to Acquisition Phase II. And if you remember
21 right, at Milestone II, that is the go-ahead decision to proceed
22 into FDA Phase III trials to prove efficacy.

23 In bold at the end is the status of where we are
24 today. So, for submission of final reports for the Phase I
25 studies, we've completed that. We have made the selection of the

1 boost component. The Phase II trials are ongoing, but the
2 interim analysis is being conducted as we speak, and we certainly
3 expect an interim report within the next 60 days.

4 There was a requirement that the manufactures
5 commit to manufacturing the vaccine. Remember that this is a
6 prime-boost, so there's two components to this vaccine. The
7 boost component has already been manufactured and is waiting for
8 us to start the trial.

9 The prime component, ten lots are required. Some
10 of those lots have already been manufactured. They are currently
11 manufacturing lots, and they will continue to manufacture lots up
12 until about January or February of this coming up year, so they
13 should be ready by the time we're ready to start a Phase III
14 trial.

15 There was a requirement to obtain FDA concurrence
16 -- not approval, but concurrence with the Phase III protocol.
17 The study design for the Phase III study has already been --
18 "approved" is the wrong word -- already been agreed upon by all
19 the parties. The protocol writing team has already been
20 established. They are, I believe I heard today, on Version 6 of
21 the draft. They expect to enter scientific review of that draft
22 next month, so we certainly should meet -- once we have a firm
23 draft that we're ready to show the rest of the world, we will
24 then take that and go to the FDA for an end-of-Phase-II meeting
25 and discuss the protocol along with other issues with the FDA at

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1 that time. So that's expected to be completed by the end of this
2 year, this fiscal year.

3 And the last was to identify a plan for sufficient
4 funding for Acquisition Phase II. At Milestone I, there was an
5 issue of insufficiency of funds that was identified. They wanted
6 to make sure that before they give the go-ahead, that we have
7 sufficient funding for Acquisition Phase II, and that has
8 recently been resolved. Next slide, please.

9 (Slide)

10 Program Managers do everything by Gant charts, and
11 I have a huge Gant chart on my wall that takes up about half my
12 wall. I didn't bring it here today, but I did summarize that
13 Gant chart in the next slides.

14 This is the product development plan. First, we
15 are going to down select among the three boos candidates in a
16 Phase II trial and, as I said, these trials are nearly complete.

17 Conduct a Milestone II in the first quarter next year. Evaluate
18 the selected candidates during a Phase III field trial in a
19 single clade environment. This is a clade E vaccine. We want to
20 give it the maximum opportunity possible to demonstrate efficacy,
21 so we're going to test it in an environment that's with primarily
22 clade E HIV viruses circulating.

23 If the vaccine proves to be efficacious, we'll
24 then submit a biologic license application to the FDA for a clade
25 E indication. At that point, if the military decided it wanted

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1 this vaccine, it could buy it. However, at this point, we have
2 only proven efficacy against a single clade, so we then want to
3 conduct a technical review to determine whether or not to test
4 this vaccine in a multi-clade environment, and whether or not
5 other vaccines that are currently in the tech-base should be
6 incorporated into the program. Next slide, please.

7 (Slide)

8 Whichever vaccines we proceed with then would be
9 evaluated in another Phase III trial in a multiple-clade
10 environment such as Africa where clades A -- well, all the clades
11 are circulating, but predominately A, C and D, and Col. McNeil
12 will go into this in a lot more detail in his presentation.

13 We then submit a supplemental BLA to the FDA for
14 now a multi-clade vaccine and, again, the military could buy the
15 vaccine at this time, if they so choose, but this will be a 4-
16 dose vaccine, and currently in the draft ORD there's a key
17 performance parameter for a 1- or 2-dose vaccine.

18 So, once we have proven this principle --
19 actually, once we've completed the Phase III trials in Thailand,
20 we then can reformulate the vaccine as a 1- or 2-dose vaccine and
21 conduct a bridging study to evaluate this 1- or 2-dose vaccine
22 against this 4-dose vaccine up there.

23 Again, submit another supplemental BLA to the FDA,
24 conduct a Milestone III transition this to fielding, and procure
25 it as a Defense Health Program vaccine, and field -- depending on

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1 the decisions you make here -- to the total force or to selected
2 forces before deployment. Next slide, please.

3 (Slide)

4 Where do we stand technically? Again, Col. McNeil
5 will go over this in much greater detail. We are currently in
6 these Phase II studies for down-selection. We are in the
7 planning stages for a Phase III trial in Thailand. The study
8 populations and the field sites have been identified.
9 Negotiations with both manufacturers and the Thai Ministry of
10 Public Health have been ongoing for over a year, and are still
11 ongoing. The infrastructure is being evaluated as we speak, and
12 upgrade of this infrastructure is expected prior to study start.
13 The protocol is in preparation and certainly will have a draft
14 in scientific review by next month.

15 Efforts to identify study populations for the
16 African trial have already begun in the tech-base. Next slide,
17 please.

18 (Slide)

19 I'm going to summarize this slide real quickly to
20 say that developmental funding for both Acquisitions Phase I and
21 Phase II are available with our current plans. Procurement
22 funding, this statement assumes that the military will not
23 procure the vaccine until we get a 1- or 2-dose vaccine. That's
24 not expected until FY12. The POM only goes out to '07, so
25 procurement by the services -- funds have not been identified for

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1 procurement by the services at this time. Last slide.

2 (Slide)

3 This concludes my briefing. Are there any
4 questions?

5 DR. LaFORCE: Questions of LtCol. Clayson? Sounds
6 like you're well on your way.

7 LtCOL. CLAYSON: The program is in relatively
8 advanced stages.

9 DR. LaFORCE: What's the relationship of the
10 candidate -- I've got the terminology mixed up -- the --

11 LtCOL. CLAYSON: The prime-boost candidates?

12 DR. LaFORCE: Yes, that's right, the prime, in
13 relation to the vaccine that's being currently field tested in
14 Nairobi, which was derived out of, I believe, the British
15 studies?

16 LtCOL. CLAYSON: Can I defer that question to Col.
17 McNeil?

18 DR. LaFORCE: Yes, because it sounds like it's the
19 same vaccine.

20 COL. McNEIL: It's the same in the sense that it's
21 a live virus vector. That's modified vaccinia ankra which
22 carries HIV genes which have been selected based upon the
23 predominant circulating viruses in and around Nairobi. That
24 approach is totally untested. We have no idea of its safety or
25 immunogenicity. The canary-pox approach has been used in

1 thousands and thousands of humans, and there's a wealth of both
2 safety and immunogenicity data. So, while the approaches are the
3 same, there's a vast body of experience and data with the canary-
4 pox approach, there is virtually none with the MVA approach.
5 But, in theory, it should do the same thing, which is to induce
6 cellular immunity.

7 DR. LaFORCE: That was my question. Yes.

8 DR. SHOPE: I'm wondering if you see any
9 inconsistency here. One of your performance requirements is to
10 prevent virus transmission, and you've discussed that. If you go
11 back to your program objective, that's not part of the program
12 objective, it's to prevent illness. Shouldn't you add that to
13 your program objective, if that's going to be a requirement?

14 LtCOL. CLAYSON: To prevent virus transmission?

15 DR. SHOPE: Yes.

16 LtCOL. CLAYSON: I'm thinking of about three
17 different ways to address that. One way is to say that it's
18 going to be almost impossible to prove that you can't transmit a
19 virus in this kind of an efficacy study. So it's not an
20 objective in that sense, it's not part of the program objective.
21 FDA-acceptable vaccine is the objective.

22 You have some other thoughts, Col. McNeil?

23 COL. McNEIL: I think that's a lot to ask of a
24 vaccine, especially a first-generation vaccine. It's virtually
25 impossible to design an efficacy trial where you could establish

1 prevention of secondary transmission, and I don't know of any
2 other vaccine where that was part of the initial efficacy trial
3 design. That's typically something that you would try to observe
4 and measure in a Phase IV study, in a field effectiveness mode,
5 not in an efficacy trial. So, I don't think it should be part of
6 the requirements that are aligned and assigned to an efficacy
7 trial and to a primary development, but it is something that
8 could be assessed in a Phase IV.

9 LtCOL. CLAYSON: And it can be assessed in a Phase
10 IV because at that point you've given the vaccine to millions of
11 people rather than thousands of people.

12 COL. DINIEGA: You showed a slide that looked at
13 the sort of historical trend for efficacy numbers as a way to
14 sort of compare why this ORD is a little different from previous
15 ORDs. What can you say about any other ways that this process or
16 the ORD itself is different from what has gone on before?

17 LtCOL. CLAYSON: Differences between this ORD and
18 previous ORDs.

19 COL. DINIEGA: Or this process for the HIV vaccine
20 versus the other processes.

21 LtCOL. CLAYSON: That's a different question.

22 COL. DINIEGA: I think that this is the first time
23 that a question concerning an ORD has come to the Board. And you
24 showed a whole listing of ORDs, and this is the first time
25 they've had to take a question concerning the development of an

1 ORD to the AFEB, so there has to be something different and there
2 has to be something significant.

3 LtCOL. CLAYSON: There are a lot of differences in
4 the program, between this program and let's say our Infectious
5 Disease program, or even our biological defense vaccine programs.

6 Probably the biggest difference, to start with, is that this was
7 a congressionally-mandated program. This wasn't a mission that
8 the DoD set out and said, "We want this, we want this, please
9 give this to us". This is something Congress said "Thou shall",
10 and the reason they did that was they saw what we were doing in
11 the idea arena and said that, "well, the Army in particular, but
12 the ID program is a product-driven program, we want a product,
13 the Army is probably best suited to do that". Whereas the NIH --
14 please don't interpret this as a slam on the NIH -- but it's
15 primarily a research organization. They are not necessarily
16 product-oriented, although products have come out of the NIH, but
17 that's not what they are driven to do.

18 Congress has sought fit to provide quite a bit of
19 funding -- a lot more funding to the NIH -- for HIV vaccines than
20 they gave to the military, but this is, first off, a
21 congressionally-mandated program.

22 MGEN. PARKER: I think it's really best to delay
23 your question until after the science is presented because Ed's
24 going to tiptoe around the tulips and you're not going to get a
25 straight answer on it now. So, let's go on with the science,

1 unless there's other questions about the development process.

2 COL. McNEIL: Gen. Parker, Dr. LaForce, members of
3 the Board, Col. Eitzen as host, I appreciate the opportunity to
4 speak here before you today. I appreciate the Board's indulgence
5 in allowing us to change the order. I thought it was probably
6 more effective for the Board to hear Col. Clayson's specifics
7 about where we are with advanced development up against what Col.
8 Scott showed as the requirements, before I stepped back and show
9 you a broader picture and the context for HIV vaccine development
10 within the DoD, talk a little bit about the role that MRMC has,
11 which I think is incredibly important for HIV vaccine
12 development, and to give you a little bit of our rationale and
13 philosophy for vaccine development as the context for what you've
14 heard so far today.

15 (Slide)

16 Col. Michael asked this question earlier. Back in
17 1994, the AFEB actually did deliberate on this. It wasn't
18 official, it was unofficial, but I was -- maybe I should start by
19 telling you I'm a Preventive Medicine Officer. I started in the
20 field as a Preventive Medicine Officer at Fort Dix, New Jersey,
21 and I was a user of vaccines in an operational context second to
22 none. Over the last 15 years, I've worked almost exclusively in
23 the field of HIV and AIDS, and for the last ten years have been
24 involved for vaccine development. And my view towards vaccine
25 development has evolved a lot over the last ten years, from a

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1 user to what it takes to be a developer.

2 This question about whether the military needs an
3 HIV vaccine was discussed back in 1993 and 1994 by the Board.
4 Gen. Moore was actually sitting here in uniform at the time, I
5 think, when the epidemiology was shown to the Board and there
6 were some discussions about the need for interventions, including
7 vaccines.

8 At that time and ever since, the question
9 recurrently has been is this a military-relevant disease? Should
10 the military sponsor and conduct prevention research? And should
11 vaccines be a part of that?

12 If the answers to those questions are yes -- and I
13 will speak a little bit more to that from my perspective in some
14 subsequent slides -- then I think it's important to realize that
15 there is an inevitable process through which vaccine development
16 must progress, which is typically measured in generations --
17 first generation, second generation, and on and on.

18 We're at the first generation. We're at the very
19 beginning of this process. In the development of a candidate
20 vaccine for a very difficult infectious disease like HIV, you may
21 need to consider that it's worthwhile to develop these vaccines
22 for the sake of generating a body of scientific literature and
23 data which is important in and of itself, and not driven
24 necessarily by an acquisition model.

25 Now, I understand that for the purposes of using

1 this product effectively and deploying it in the field, we need
2 to follow the acquisition model, but for the purposes of the
3 first-out-of-the-block HIV vaccine to decide whether or not it's
4 possible to protect individuals by adaptive immunity, I believe
5 that you need to look at this maybe from a perspective that's a
6 little bit broader than just acquisition-driven, and that a
7 success, as measured by showing that you do achieve the goals of
8 your trial and you show efficacy, will be met with increased
9 interest funding and pushing forward to a vaccine that ultimately
10 will meet the acquisition requirements set forth by Col. Scott.

11 (Slide)

12 The epidemiology of HIV in the military has been
13 very well described for 15 years because of the recurrent and
14 routine testing programs that we have in place. This is the most
15 current complete data that I have to show you. It's for the
16 Army. Presently, 1999, there were over 320 new HIV infections
17 which occurred in Army forces during that interval year. I
18 submit that this is an important infectious disease, it's one of
19 the most important infectious diseases that an active duty force
20 and a Reserve and National Guard force will face.

21 It is a lethal infectious disease. While there
22 have been great strides made in chemo-prevention and
23 therapeutics, the lethality of the disease is still uniform, it's
24 just spread out over a much longer period of time.

25 It's important also to keep in mind that this does

1 cause signs and symptoms of illness in the majority of
2 individuals who are infected usually within two to four weeks of
3 acquisition of the infection, and that can actually debilitate
4 the soldier for a period of weeks.

5 It also, of course, would result in other forms of
6 potential casualty which could affect or impact the deployability
7 of the soldier.

8 And data that we've been acquiring since 1998 and
9 on shows that at least 10 percent of our infections are occurring
10 with non-indigenous strains of HIV which must be acquired
11 overseas. So, it is a deployment-associated problem.

12 (Slide)

13 We need prevention and we need a global HIV
14 vaccine for a number of reasons. I'll break these into
15 peacetime, wartime, and one that Gen. Parker, I think, brought to
16 our attention and reinforced our thinking on last week, is a
17 national security issue.

18 In peacetime, we obviously have military
19 personnel, especially medical personnel that are deployed to
20 peacekeeping and humanitarian missions in areas of
21 hyperendemicity, where we could be serving with military
22 populations, especially in Africa, that have very high
23 prevalences of HIV. We could be involved in co-casualty
24 situations with massive blood exposures, such as the U.S.S. Cole
25 or Colbar Barracks where it's important, I think, to have every

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1 protective measure available in your armamentaria.

2 During wartime, of course, if we look at the
3 history of S TIs during wartime, we have a historical predictable
4 threat to our force.

5 And as a national security issue, I think instead
6 of thinking of this infectious disease only as a "warstopper",
7 which many could argue successfully that it is not, we need to
8 think about this as a potential "warstarter" because of the
9 destabilizing effect that it can have on less developed countries
10 where the prevalence and incidence of infection is so high and so
11 much of the infrastructure and leadership and workforce is being
12 degraded.

13 (Slide)

14 The Division of Retrovirology at Walter Reed has
15 been in the business of HIV research for about 15 years we've
16 been involved, and this is how we're structured to conduct
17 vaccine research and development. I won't dwell on this. I
18 would say that we are one of the two important Federal Government
19 players in HIV vaccine development.

20 (Slide)

21 The program is about \$25 million a year. We've
22 received about \$10 million a year in congressional plus-up almost
23 every year. This is about a tenth of the size of the U.S. NIH
24 program, but we are unique in that we are a highly directed
25 program focused on development of vaccine. We spend about 70

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1 percent of our dollars in vaccine research and development. You
2 can see here, prevention is very much of a priority over research
3 and development in the clinical front within our program.

4 (Slide)

5 As I mentioned, this is a long-term undertaking.
6 Basic research and development through concept exploration
7 through product development. On average, it takes about 12 years
8 for private industry to develop a pharmaceutical from the
9 benchtop to the point where it's licensed by the FDA and used.

10 For a biologic, that would be a short time period.

11 For a hard infectious disease like HIV/AIDS where we really
12 don't know what it takes to protect individuals, then I think
13 we're looking at something that's going to be measured in
14 decades, and we are at the very beginning of that.

15 (Slide)

16 It is an iterative process. We look at a number
17 of biological candidate vaccines. We assess them for their
18 safety, for their induction of immune responses. If we're not
19 satisfied, we go back to the drawing board and we move forward
20 with addition.

21 So far in the human experience, there have been
22 about 60 HIV candidate vaccines which have been in the clinic in
23 human Phase I or Phase II studies. The majority of those studies
24 have been conducted by sponsorship from the U.S. National
25 Institutes of Health, and we have looked at that data and used

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1 that data to make decisions to selectively move products forward
2 and assess them in our own hands. Based upon that, we've
3 enjoyed, I think, an improvement in the time course that it takes
4 to generate important data to make decisions about moving
5 products to Phase II trials.

6 (Slide)

7 In our own hands, we've immunized in excess of 800
8 individuals in Phase I and Phase II studies. Most of those
9 studies have been conducted in Thailand. We first began working
10 in collaboration with the Thais in 1991. At that time we felt
11 that this would be an exceptional environment to work
12 collaboratively to assess candidate vaccines because of the
13 nature of the epidemic in Thailand. It was very widespread. It
14 was very severe. It was throughout the general population, and
15 it was not confined just to behaviorally circumscribed groups.
16 We had a long track record of effective collaboration with the
17 Royal Thai Government and the Thai Army, and there was a real
18 desire to do this work.

19 We've moved forward together with them through a
20 series of Phase I/Phase II studies, to a point now where we are
21 at pivotal Phase II studies, as Col. Clayson mentioned, looking
22 at a combination ALVAC-canary-pox prime with recombinant subunit
23 boosting.

24 (Slide)

25 HIV vaccine development is difficult for a number

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1 of reasons. I've been cautioned about this first term,
2 "correlate of immunity". It's a little bit misleading. What
3 this means to people who don't talk this language all the time,
4 we're really talking about what's required to protect people, or
5 correlate of protection. We don't have the luxury of being able
6 to observe humans who have gotten infected with HIV and have
7 cleared the infection. There haven't been very many instances
8 where we've been able to identify populations who are routinely
9 and predictably exposed and have failed to become infected, and
10 been able to correlate that with immune responses.

11 There is suggestive data to suggest that both
12 cellular immunity and humoral immunity are important, but there's
13 no certain information about what it will take in order to have a
14 vaccine that works.

15 We know that animal models are widely diverse,
16 there are a number of them, and the bottom line is none of them
17 are valid at this point because the only way you can validate an
18 animal model is to have protected humans and then go back to see
19 which animal models were predictive of human protection. We
20 won't have protected humans until we have an efficacious vaccine.

21 As Dr. Clayson mentioned, HIV is known by its
22 genetic diversity. It is widely genetically diverse throughout
23 the world, and we are uncertain what this genetic diversity means
24 for immune response and protection induced by vaccines. So, we
25 need to go through this systematically. We wanted to begin by

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1 asking a question in a single environment where there was one
2 strain of HIV circulating and a vaccine that was matched to that
3 strain and say, "Under the best of circumstances, can we induce
4 protection with a vaccine?" Then we would look further to see
5 how broad that protection was.

6 (Slide)

7 So, again, we're at a point now, after we began
8 these clinical studies in 1995, we're at pivotal Phase II
9 studies, looking at a combination of the canary-pox boosted by
10 the recombinant subunit proteins, to see whether or not we're in
11 a position to move forward to the efficacy trial that Dr. Clayson
12 described.

13 (Slide)

14 This is the diversity that I was talking about.
15 We have full length sequenced a number of viruses from throughout
16 the world and, as far as you look, you can find genetic
17 diversity. The ideal situation for assessing vaccine-induced
18 protection was selected in the bottom, where we are matching
19 viral antigens to the circulating strain, which is very similar
20 from person-to-person throughout Southeast Asia and Thailand.
21 Very little diversity is seen there.

22 (Slide)

23 WRAIR's approach is very applied in terms of
24 vaccine development. We move things forward that make sense
25 empirically. We will make changes to our strategy based upon

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1 emerging science which is compelling.

2 In the field of HIV and AIDS, and specifically as
3 reference to vaccine development, there's been very little
4 compelling science over the last ten years to tell us to move in
5 directions other than the ones that we're moving in. And we
6 really think it's important the first time out of the blocks to
7 prove the concept under the most advantageous conditions that are
8 possible.

9 (Slide)

10 So our approach is to decide what immune responses
11 we want to induce. We either design or obtain products that do
12 induce those responses. WE verify that through Phase I and Phase
13 II studies, and we try to set milestones that we think are
14 appropriate for moving forward. If milestones are met, we move
15 to the next step. If compelling science emerges that tells us
16 that that what we're doing doesn't make sense, then we'll make
17 changes to that strategy. But, ultimately, we need to move to
18 the field. There are endless debates about whether a vaccine is
19 good enough to be efficacy tested. Everybody has an opinion, and
20 nobody knows what the truth is. The only way to really find out
21 whether these approaches will work is to go to a field efficacy
22 trial.

23 (Slide)

24 We initially wanted to be in a position to develop
25 candidate vaccines that were very good in inducing antibodies, a

1 second class that were very good in inducing cellular responses,
2 and then combine the two to induce both. And early in our work
3 in Thailand, the incidence was so high we felt we could do a
4 comparative trial there where we could look at all three
5 approaches, called the best of a vector class strategy with a
6 common placebo group.

7 (Slide)

8 As you probably know, the Thai government and the
9 public health system within Thailand has done a fantastic job of
10 counteracting the epidemic in the country. The incidence of HIV
11 has declined throughout the country, still to levels that I would
12 consider to be high, unacceptably high, but instead of being
13 measured on the order of 5-10 percent a year, it's somewhere on
14 the order of .5 to 1 percent per year.

15 So we had to take a reductionist view here, and we
16 thought the best way of moving forward was to pick the candidate
17 that induced the most complex repertoires of immune responses,
18 which is the prime/boost strategy, which is, again, the one that
19 we're talking about now is an ALVAC which contains the HIV core
20 gag gene, the premerase gene, and the envelop gene, the envelop
21 being derived from a primary clade E isolate, which is very
22 similar to the circulating virus in Thailand.

23 The recombinant protein boost is a bivalent boost
24 that includes a clade E genotype E virus and a genotype B virus.
25 We will do an unblinded interim analysis over the next 30 to 60

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1 days to see whether or not our milestones are being achieved.

2 (Slide)

3 Before we started these trials in collaboration
4 with our industry partners and with the Thai government, we
5 established milestones that had to be met by these candidates in
6 order to move to a field efficacy trial. They had to do with
7 both induction of antibody and induction of cellular immune
8 responses, and it's the point of this interim analysis to see
9 whether we need these milestones. If the vaccines are safe and
10 if they are immunogenic as the milestones we've set here, we
11 would move forward. If they are not, we will not, we will move
12 back in the iterative process and go back to the technology base
13 and try to push something forward that does a better job than
14 what is currently available to us. We feel collectively, as a
15 scientific community, that these were reasonable milestones to
16 expect of a first-generation candidate to move to the field.

17 (Slide)

18 We also needed to have the same kind of criteria
19 for the population which we would invite to participate in the
20 trial. As you know, HIV is a very dynamic process, and we needed
21 to make sure that we had a population that had measurable
22 predictable incidence, good follow-up, predictable low migration,
23 in-and-out migration, and interest in participating in the trial.
24 We've been working for five years in Thailand to achieve that,
25 and we are there with the populations in two southern provinces

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1 in Thailand.

2 (Slide)

3 The trial that we're talking about is a community-
4 based trial in two provinces, Rayong and ChonBuri, that would be
5 conducted at eight district hospitals and 40 district health
6 sites. There will be 15,000 volunteers in this trial. That is
7 driven by the incidence of infection that we expect to observe in
8 the study, and the level of efficacy that we are powering the
9 study to detect.

10 By definition, this product is given over a period
11 of 6 months. It's given at Day 0, at 1 month, 3 months, and 6
12 months. So, when we are talking about the ORD, this is the
13 reality of what a first generation vaccine will take in order to
14 induce immune responses that we think are meaningful and should
15 be measured to see whether or not they have a biological impact
16 for efficacy. We obviously will not meet a 2-dose or 1-dose
17 objective with this, nonetheless, we believe that this product is
18 very, very important to assess for its immunogenicity, and we
19 won't be able to do better than this until we prove that this
20 combination is able to induce efficacy. The study will last for
21 two to three years, depending upon the endpoint accrual that
22 occurs during the trial.

23 The primary endpoint is infection, sterilizing,
24 immunity, and the study is powered to detect a 50-percent
25 reduction in infection hazard in individuals who are immunized

1 versus placebo. A secondary endpoint will look at circulating
2 plasma viral load and CD4 count. We are powered in order to be
3 able to see as small as a log difference in vaccinees versus
4 placebo recipients. That difference is biologically very
5 meaningful for the subsequent induction of disease.

6 It is also very meaningful for perinatal
7 transmission for reduction in mother-to-infant transmission.
8 There is absolutely nothing known about the meaning of this for
9 sexual transmission in adults, but I think that we can infer
10 based upon its impact on disease and on mother-infant
11 transmission, that there also would be a significant impact on
12 sexual transmission. The study would begin in the Summer of 2002
13 and would last for four years, at a cost of about \$5 million per
14 year.

15 (Slide)

16 And our time line is from concept in the Fall of
17 1998. We are now at the first green star, making a decision
18 about down selecting and meeting our criteria to move into an
19 field efficacy trial by Summer of 2002.

20 (Slide)

21 I'm not going to go through this, I'm just leaving
22 this. This is in your packet. It's to let you know that we do
23 have an active technology base program. We feel that you have to
24 have a very viable technology base to move forward if you are
25 committed to vaccine development, it can't be a one-shot deal.

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1 And we have a number of candidate vaccines that we're very
2 excited about that we feel will be improvements on the existing
3 first generation candidate which we do believe, if it meets
4 criteria, is ready to go to efficacy testing. These will not be
5 available for efficacy testing anytime in the next three to five
6 years at a minimum. That's now long it takes to go through Phase
7 II testing.

8 (Slide)

9 Let me just end by touching on the four points
10 that were brought up in the ORD on efficacy transmission, being
11 able to differentiate between vaccinee and infected, and the use
12 of the vaccine.

13 Again, for the purposes of what we're doing here,
14 infection is the measure of efficacy. If we go to the FDA with
15 this plan, primary efficacy measure is a 50-percent reduction in
16 infection. So, this would be licensed by the FDA or not, based
17 upon its ability to do that.

18 A secondary outcome measure is reduction in viral
19 load, which would then be associated with a decreased occurrence
20 of disease, the measure by which most vaccines work. We will not
21 be able to seek licensure based upon this as a secondary outcome
22 measure. It will be, I think, very, very important information
23 to have because a positive finding in this realm would cause
24 industry to go back and reinvest itself into trying push forward
25 with improved vaccines that will do a better job at both

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1 preventing infection and disease.

2 The issue of transmission, again, I think this is
3 something that is impossible to ask of a first generation vaccine
4 in an efficacy trial, and it's something that could be assessed
5 in a Phase IV setting.

6 The ability to differentiate between a vaccinee
7 and an infected individual for this class of first generation
8 vaccines is quite easy, using our standard immunoassay Western
9 Blot diagnostic algorithm. These vaccines, unfortunately, are
10 not able to induce antibody that would result in a diagnostic
11 pattern on our standard testing algorithm. We wish they did,
12 they'd probably be better vaccines if they did, but they don't.
13 And so we feel that we can reliably differentiate with the
14 existing EIA Western Blot.

15 As Col. Clayson mentioned, in over the course of
16 probably the next six months, the FDA will be looking at
17 licensing nucleic acid testing for use in bloodbanking. In the
18 rare instance of a false-positive, an individual who is
19 vaccinated and not infected, the use of a nucleic acid test would
20 be able to be an infected differentiator, it would actually show
21 us that the person had viral genome in their system and not an
22 immune response. We should have that tool available to us as
23 soon as it's available for bloodbank use.

24 And, finally, in terms of the issue of how we
25 would use it, I would just ask you to consider again that we are

1 at the beginning of this process, and this is a very difficult
2 infectious disease, and kind of think of this, that we have to go
3 through a crawl, walk, jog and run process, and the combat
4 developers are asking us to run with this vaccine. We're not
5 quite ready to do that yet, but we think these vaccines are ready
6 to assess whether or not they are crawling, and the only way to
7 do that is to put them into the field and do a field efficacy
8 trial.

9 That concludes my presentation. Hopefully I've
10 given you a little context for why we are where we are, as Col.
11 Clayson described to you initially, and happy to answer any
12 questions. Thank you.

13 DR. LaFORCE: Questions for Col. McNeil? How
14 large will the study be in ChonBuri?

15 COL. McNEIL: The entire study is 15,000
16 individuals. ChonBuri will more than likely recruit 9- of the
17 15,000.

18 DR. LaFORCE: And that's with a power of --

19 COL. McNEIL: That's with 80 percent power to
20 detect a 50-percent reduction in infection hazard in the
21 vaccinees versus the placebo recipients.

22 DR. LaFORCE: And what's the current prevalence
23 rate there?

24 LtCOL. CLAYSON: The incidence rate which we have
25 measured in the population is .7 percent per year. For the

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1 trial, we used the lower boundary of the 95 percent confidence
2 interval to design the study. We wanted to absolutely make sure
3 that we had adequate power in the study, so we were very
4 conservative in using conservative incidence estimate.

5 COL. MICHAEL: Would it be safe to estimate that
6 you might have to increase the trial size by an order of
7 magnitude to rule out transmission differences?

8 COL. McNEIL: I don't think an order of magnitude
9 is big enough.

10 COL. MICHAEL: It would be talking about a
11 significant increase in trial size.

12 DR. ALEXANDER: John, I was just curious about the
13 gender distribution of the intended participants. This is an
14 entirely male population?

15 COL. McNEIL: No, this is a community-based study.
16 The approach to the community would be to take a representative
17 sample of the community. Of course, these are individuals that
18 will listen to public service announcements and targeted
19 advertisements and then will select themselves to show up. Our
20 cohort development projects have been in both males and females,
21 so it isn't an exclusively male-directed project.

22 COL. DINIEGA: The incidence you mentioned, John,
23 the general population is overall --

24 COL. McNEIL: It's an overall population which is
25 made up of both males and females. There is not a significant

1 disparity between the infection rates in males and females in
2 these two communities.

3 DR. HERBOLD: John Herbold, San Antonio. I
4 commend you all in this and having 15 years ago was dressed by
5 Gen. Ratman when there was a \$6 million congressional plus-up for
6 HIV research. Adm. Zimble was also around that dressing down.
7 But did I miss something about what the military operational need
8 is for -- and I'm trying to reflect on how I would react to
9 trying to answer some of these questions, and I would have to
10 know what the military objective is so, in a simplistic manner, I
11 would state one question might be the goal of the vaccination
12 program is to prevent infection in an occupational setting --
13 troops deployed, exposed to blood or blood products, or exposed
14 in avocational activities incident to military deployment.

15 Another question might be, prevention of infection
16 in troops who are going to be used as part of the walking blood
17 bank. And I guess my question is, did I miss the questions that
18 would precede this long laundry list of questions, because I'm
19 having trouble putting it in context.

20 MGEN. PARKER: Mr. Chairman?

21 DR. LaFORCE: Yes, of course.

22 MGEN. PARKER: You didn't miss anything. Let me
23 try to put this in perspective of what's on the plate today. The
24 Department of Defense, ever since that redressing of Gen. Ratman
25 to you, has been engaged heavily either through a congressional

1 appropriation or through a direct appropriation in developing a
2 vaccine for HIV.

3 The whole program was focused, other than clade B,
4 for the simple reason that it was evident that NIH and other
5 bodies of research would immediately jump on clade B as it was
6 the infective species on the Continental United States, and the
7 direct U.S. public health threat. So, the whole program was
8 focused away from B and looked at the other clades worldwide.

9 The program has survived for 15 years, and if laid
10 out against the other activities that are working in this area --
11 NIH, I think it's ALAC, a couple of others -- you could four up
12 there and you could put the DoD there -- you would find that the
13 DoD not only has a very defined research base, but they've
14 developed a product, they've developed a safety and efficacy, and
15 they are going into field trials. And if you look at the others,
16 you will see empty blocks and goose eggs where others have not
17 completed that.

18 So, we have a scientific program that has gone
19 into acquisition, and now being -- because it represents \$35
20 million of research dollars, I believe it's being looked at for
21 the possibility of where we could put that other \$35 million.
22 That is not my position. I believe in this program, and I'm
23 going to make a couple of comments to the Board about this, and I
24 want to be on record for it.

25 If the Armed Forces Epidemiology Board felt that

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1 adenovirus is a requirement and a vaccine for adenovirus is a
2 requirement, I think they so should agree that HIV vaccine is a
3 requirement for the military. In the last calendar 12 months,
4 only one documented case of death due to adenovirus has occurred,
5 possibly two, but not conclusive. The number of people just in
6 the Army that are contracting HIV is 330. If you add the Navy
7 and the Air Force, I don't know what the total number is, but
8 it's somewhat over 500.

9 It's a behavioral thing, and although we have good
10 preventive medicine, education and training, soldiers, sailors,
11 airmen and Marines are not behaving in the most perfect construct
12 during deployments.

13 And so I say it is a problem for the military, and
14 this is why I say it. First of all, there is a culture in the
15 military that believes that the military don't engage in this
16 risk. Well, we've proven that they do by numbers.

17 The military denies deployment of individuals with
18 HIV disease, but they do not separate them from the force. And so
19 each of these individuals add to the total numbers that we can
20 bring into the force in uniform. If we could have prevented
21 these individuals from getting HIV, they would be usable members
22 of the military force to deploy anywhere in the world.

23 Now, the walking blood bank, as you bring up, is
24 the rationale for the nondeployment, so that we could have a
25 living, walking blood bank. But, if you deploy, protection or

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1 immediate screening of those deploys before sharing blood is not
2 done. And we all know around this room that early infection is
3 the highest viral load during HIV, so we don't seem to have a
4 continuity in our policy about the walking blood bank.

5 If we believe in traditional definitions of
6 personal protection from a disease that not only is prevalent but
7 causes death, all of those things above uphold the fact that we
8 should prevent those in uniform and vaccinate them against HIV.

9 As Dr. McNeil said, I proposed a little different
10 look than the traditional look for the 21st Century about how we
11 do things in the DoD, and the traditional structure is that we
12 have an individual, male or female, in the service, and we're
13 going to protect them against disease because they are going to
14 an endemic area. That's a very traditional look at why we protect
15 individuals. If you up that to a national security level, I
16 think if we -- and you could very well say the NIH can do this,
17 or somebody else can do this, but we're so far along with our
18 science I am saying, first out the door with a vaccine, hua,
19 because what's the goal here? What's the goal? The goal is to
20 prevent HIV infection and, you know, if we don't stop this
21 disease -- I'm speaking to the choir around this table -- the
22 infrastructure in Africa and the infrastructure in Russia will go
23 to you-know-where in a handbasket and, for sure, we'll be
24 deployed because there will be chaos and war, and we'll be
25 deploying our folks probably without any protection.

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1 So, I think that cycle of events needs to be
2 thought about under a national defense posture rather than the
3 traditional "protect the soldier, protect the Marine, protect the
4 Air Force", and does the DoD play a role in that particular
5 thing.

6 I say right now that the DoD program is advanced
7 and probably a leader in the field of producing a product against
8 a couple of the clades of HIV, and through that work I'm sure the
9 keys to developing vaccines on the other clades will be an easier
10 road to run.

11 So, I say to the Board that the Board could say
12 sort of plus-minus on the military requirement. I'd like you to
13 make a positive statement about that requirement, but you could
14 also make a statement in conjunction with that that the DoD
15 should continue to produce a vaccine because of their science and
16 acquisition expertise -- at this point, you have 15 years of work
17 onboard and getting ready to go to a Milestone II.

18 I think the ORD is an illusionary document, and I
19 say that with all professional feeling for the people who are
20 required to do ORDs, but it's not based on true science, and it's
21 perhaps drafted to prevent the DoD from continuing in this area.

22 I believe that the 90-percent effectiveness on a
23 vaccine for a complicated RNA strain or a DNA virus is
24 uncomprehendable. And as I talk to other pharmaceutical
25 companies, when we talk about malaria, TB and HIV, we talk about

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1 spiral developments of vaccines in these difficult areas, and not
2 the ultimates of a perfect vaccine the first time out of the box.

3 I think the Board really has to struggle with the
4 fact that other vaccines have been okayed to be produced at an
5 80-percent efficacy, but this one has to be 90 percent.

6 The dosing schedule is also illusionary and not
7 based on science. Sure, the CINC -- if you ask a 4-star CINC
8 what they want, they actually want one shot for everything one
9 time -- one time and nothing else has to happen. Now, that's
10 perhaps in the future possible, but right now I think we have to
11 look at it in incremental steps and keep the goal in mind --
12 prevent HIV. If it takes 4 shots, then 4 shots should be the
13 policy, and the Department of Defense and other public health
14 agencies would accommodate the 4 shots.

15 And I'm going to end there. I've said my piece,
16 but I think the Board has a difficult thing on their plate, and
17 it was thrown on the plate with perhaps some hidden agendas, and
18 I didn't want those agendas to go unnoticed and hidden. The
19 combat developer could say what they want, but the combat
20 developer really hasn't come to the table for good scientific
21 discussion for developing a first generation vaccine as a
22 requirement.

23 Now, you could go back and go to simpler -- okay,
24 maybe the criteria are all shot up, but maybe the Board, if the
25 Board just wrestles with the fact of is it or is it not a

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1 military requirement, then I think in the future the early
2 criteria for a milestone decision could be rerun and reworked
3 among the scientific community and the acquisition community.

4 DR. LaFORCE: Questions? Actually, this is a good
5 segue for a break. Let's break until 3:00 -- oh, I'm sorry.

6 LtCOL. BERTE: You made a statement relating to
7 how to approach it. It seems that there is a parallel here with
8 other acquisition programs in terms of the block approach of
9 large acquisition programs where you recognize you are only going
10 to reach a certain level of capability, but it's important to get
11 that capability out there, and then you come forward with a new
12 ORD for the next block that has an increased capability, and this
13 certainly would fit into that approach in terms of coming up with
14 Block 1 is going to be less than 90 percent, maybe multiple
15 doses, or much more, with the understanding that there's other
16 things coming down the chute and you can more realistically in
17 Blocks 2 and maybe 3 improve on that.

18 So, it seems like that kind of approach which is
19 well accepted in the acquisition field, would fit in with the
20 requirements to have an open ORD and yet allow for the fact that
21 it's a very difficult project.

22 COL. MICHAEL: It should be said that an ORD is
23 not a fixed document, it's a living document, it's dynamic, is
24 that not correct?

25 MGEN. PARKER: Well, it's -- when you get to

1 Milestone II, it's pretty fixed because I'm the milestone
2 decision authority, and it's fixed at that point because I have
3 to make my decisions against the criteria on the exit criteria of
4 the ORD.

5 COL. MICHAEL: And then another point is, I'm sure
6 no matter what we set -- if we set it at 80 percent and it comes
7 out 78 percent, it will be a licensed vaccine, and the DoD will
8 have to decide whether or not it wants to use that licensed
9 vaccine. That's a fact of life. A 78-percent vaccine is going
10 to be licensed, I would bet, if it's safe and efficacious.

11 DR. LaFORCE: Try 65.

12 (Simultaneous discussion.)

13 DR. LaFORCE: Rosie.

14 DR. SOKAS: It strikes me that you could have all
15 kinds of criteria that are totally unrealistic, and all you do is
16 either make them ridiculous and a laughing stock, or you -- I
17 mean, speaking for everyone around the table, I can't imagine
18 that there's anybody here that wouldn't say go for it, as long as
19 you're not making people ill and killing them, which is, you
20 know, presumably not going to happen here, and as long as you
21 have some measure of efficacy. And I actually think that the
22 ability to distinguish between true infection and seroconversion
23 is an important criteria, so there probably are a few important
24 criteria, but they are certainly not the endproduct result that -
25 - I mean, this is not the way science is done.

1 DR. LaFORCE: Ben?

2 COL. WITHERS: Sir, I want to ask a question
3 primarily to -- I could guess at the answer, but I would like the
4 Board to hear your answer. What is about this question that
5 makes this fundamentally different? Col. Diniega's already
6 pointed that this is the first ORD that's been presented to the
7 AFEB for opinion. Why is it that we're here today? What is it
8 about the development of this vaccine as opposed to others that's
9 brought these two major commands, if you will, to this point in
10 disagreement or in a tussle, and why this -- what's going on
11 that's different?

12 MGEN. PARKER: Well, I think the basic question
13 is, is this a disease of military importance, and should a
14 vaccine be produced against it? I believe there's a lot of
15 people out there -- and I talked about illusionary thinking and
16 not being in contact with the real science -- that truly believe
17 that HIV is not a problem for the military and, therefore, the
18 DoD research base and the DoD acquisition structure doesn't have
19 to be concerned with this at all, and this is NIH's problem, and
20 academia, and the CDC, pure and simple.

21 ADM. ZIMBLE: First of all, I want to thank you
22 for allowing me to come, inviting me here, but as a former SG,
23 I've asked questions of the Board, and there's really only one
24 question. Let me underscore what Gen. Parker's one question, and
25 that should be an overwhelming "yes", that it is militarily

1 relevant. The rest of the questions asked can have to wait until
2 you've got a product, and then knowing what the parameters of the
3 product are, and then making policy regarding its use. But the
4 key question right now -- and I will tell you that funding is
5 dependent upon it -- is specifically whether or not this is
6 militarily relevant to have the vaccine, and Gen. Parker was
7 quite articulate in defining the relevance.

8 DR. LaFORCE: Questions or points?

9 (No response.)

10 If not, let's break -- well, timing is perfect.

11 Let's break until 3:00 o'clock.

12 (Whereupon, a short recess was taken.)

13 DR. LaFORCE: What we originally had scheduled for
14 the rest of the afternoon until about 4:30 or 4:45 were
15 subcommittee meetings for the Board. Given that Steve Ostroff's
16 plane was canceled -- he was to get here at 11:00, but his plane
17 was canceled, so he's either somewhere in transit, but he
18 obviously won't get here until late this afternoon or tonight --
19 so what I would propose, that makes a bit more sense, given that
20 Steve won't be here until tomorrow, if we could either continue
21 discussions, or open up the discussions along the lines that we
22 just left, and then hold the subcommittee meetings or discussions
23 tomorrow, would that be all right -- because I really would not
24 want to go ahead with a subcommittee meeting, given all the
25 materials that are going to be discussed, without at least having

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1 Steve around. In point of fact, one of the reasons that we
2 scheduled this was to accommodate his schedule. Yes?

3 COL. DINIEGA: Dr. LaForce, all of the issues that
4 are going to be raised today have been raised today, and tomorrow
5 is the Infectious Disease Subcommittee. So, really, the issues
6 are only for that subcommittee, and in the past sometimes we've
7 just stayed as a body because there was only one issue that would
8 involve a lot of people, only one subcommittee.

9 DR. LaFORCE: As I recall, we did that last time.
10 Maybe that makes sense. Perhaps we could more profitably just
11 continue the discussions that we were -- or the topic that we
12 were discussing before we broke up in terms of the HIV vaccine.
13 If you wish, we can continue that discussion this afternoon.
14 What I would ask Board members is -- I don't think it's necessary
15 to have a closed meeting or anything for that particular
16 discussion.

17 As you know, one of the issues that I really feel
18 strongly about is transparency, and so if we could -- I don't
19 have any problems -- unless other Board members do -- we do have
20 an Executive Session sometime tomorrow afternoon, so if there's
21 anything for the Board that we want to discuss in-camera, that
22 would be perfectly fine at that time. But for the rest of the
23 discussions, unless someone has any objections one way or the
24 other, I would just suggest that we just continue working, if
25 that's all right.

1 Okay. We need some feedback now from members of
2 the Board who have been quiet. Linda. I'm going to go around
3 and pick on people in terms of just feedback, and there are a
4 couple of things that you could feel free to discuss. One is the
5 issue of participation in terms of the -- it's not going to be an
6 Advisory Committee -- where's Rosie, I've got to use the right
7 words -- work group, we'll call it, that Vaccine Work Group
8 issue, and then the second is the more complex question in terms
9 of HIV vaccine issues that were brought up.

10 DR. ALEXANDER: The HIV thing, I guess I remarked
11 to a couple of people at the break, it's amazing that even DoD is
12 not immune from the politics of HIV. It's an organization that
13 deals with HIV in terms of public service, it's amazing sometimes
14 the complexity of issues and where the source of the conflict
15 really lies. Sometimes we're forced to use science to defend
16 things that really have their origins in stereotypes or
17 misconceptions or just attitudes about HIV, and I guess this, you
18 know, again, may be another example of that. I think it's
19 important that if we feel strongly about HIV being a militarily
20 relevant disease, that we say that in the strongest language
21 possible, given the complexity of these issues.

22 DR. LaFORCE: Bill.

23 DR. MOORE: I don't know whether I should recuse
24 myself from this discussion or not because I was the HIV Project
25 Officer for the Army for seven years, and I already have my mind

1 made up on this issue.

2 DR. LaFORCE: But you are a member now of the
3 AFEB, and I think that -- I would think that prior
4 responsibilities being what they are, we're actually vitally
5 interested in your opinions right now.

6 DR. MOORE: Well, one of the sets of deliberations
7 that I've been involved in -- and I think John will recall that
8 when we first started talking about development of a vaccine
9 because even at that point the Retrovirology Group at WRAIR had
10 made a lot of progress. We understood a lot about the disease,
11 and because of the epidemiology studies that had been done on
12 recruits and on retesting, we knew an awful lot about the disease
13 at the time.

14 Ethical issues came up in those discussions, and I
15 didn't hear anything about the ethical issues related to the
16 vaccine development, vaccine administration, whether or not this
17 would be voluntary and, as Linda has already said, there
18 continues to be stigma associated with the acquisition of HIV
19 infection certainly here. So, those are all issues that I think
20 the Board needs to take into consideration in arriving at a
21 position.

22 DR. LaFORCE: David.

23 DR. ATKINS: Just as a point of clarification, is
24 one of the reasons this has come up is because the funding theme
25 has changed so that this is now competing in a way against other

1 funding that it has not previously?

2 DR. LaFORCE: Rick, would you mind sort of talking
3 to that point in terms of the funding issues and the fact that it
4 sort of -- I'm sorry --

5 COL. McNEIL: It's not here because of any change
6 in funding. I don't believe that this question is before the
7 Board because of funding issues. The program, for many, many
8 years, was not funded as a part of the program, objective
9 memoranda of the stable funding of the President's budget, but
10 since 1998, we have been. The advanced development -- a
11 transition of some of those funds to advanced development was
12 made beginning in 1999, and continues to be in the budget for the
13 foreseeable future. So, I don't think that there's anything here
14 that's related to competing -- other programs competing with this
15 money, or a new influx of money into this program, I think
16 there's other motivations for why the question is before the
17 Board that don't have to do with funding.

18 I can make a quick remark about ethics. We
19 operate now in the field of HIV vaccine actually in all
20 biological research in the field under, I think, the most
21 complete and intense ethical scrutiny and guidelines that have
22 ever existed. We comply fully with all of the ethical
23 requirements as set forth by our own system, by the United States
24 Government through their Code of Federal Regulations, the United
25 Nations AIDS program, WHO, and the new programs of the NIH. So,

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1 we have five layers of ethical review of every research proposal
2 that goes forward, and there is ethical oversight in the form of
3 DSMBs which occur with all our trials.

4 LtCOL. RIDDLE: Col. McNeil, form the funding, the
5 HIV program is really not a composite part of the MIDRP?

6 COL. McNEIL: Yes, it is a part of the MIDRP.

7 LtCOL. RIDDLE: But it doesn't compete with any
8 other MIDRP priority?

9 COL. McNEIL: It does not compete.

10 LtCOL. RIDDLE: Because you all have heard before,
11 the Military Infectious Disease Research Program, the competition
12 within the MIDRP, what gets funded and what doesn't. Even though
13 this program is part of the MIDRP, it's POM'ed, the dollars are
14 POM'ed for plus additional congressional plus-ups, but it doesn't
15 take away from the other priorities in the existing MIDRP.

16 LtCOL. SCOTT: It was I who asked permission of my
17 boss to bring this question to this Board. I tried to talk Ben
18 Diniega into letting me bring it a year and a half ago. Col.
19 Withers is a softer touch. And it was I who drafted the
20 question, got it approved in my command, and it was I who sent it
21 up and pushed getting it here. And the reasons are as follows,
22 but I would like to submit a disclaimer.

23 We, in my command, are not trying to stop advance
24 development of an HIV vaccine, nor to terminate research, nor to
25 see the money redirected. We are fully cognizant that this is

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1 the absolute best science going on in the development of HIV
2 vaccine on the planet. We're fully cognizant this may be a
3 continent-saving vaccine, if not a planet-saving vaccine -- and
4 that might be a bit melodramatic -- but certainly a continent-
5 stabilizing vaccine is in its potential.

6 We have named this one of the top five out of 30
7 militarily significant infectious diseases as far as endemic
8 disease threats. We did vote it low in one prioritizing venue,
9 because it has its own money stream. So, we voted it low in one
10 voting iteration recently, but that does not mean we have any
11 posture that this is not militarily significant. It is
12 enormously significant, sometimes in an operational setting, but
13 largely in force development.

14 So, we did not ask permission to bring the
15 question because we want to kill it, but I sit at my desk with
16 written comments from major command surgeons that say four doses
17 is absolutely unacceptable, we can't do this, can't administer
18 it. Several from major command surgeons. From infectious
19 disease researchers at the colonel level in this command who say
20 four doses is impossible to administer. I can't throw the
21 comments away.

22 I have a statement from the Surgeon General's
23 Infectious Disease Consultant that 80 percent is far too low.
24 Certainly it needs to be higher, 90 is appropriate. I can't just
25 throw it away or wish it away. I can't rebut it by saying I

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1 talked to some nice guys and they told me -- you know, the
2 science guys and the advance developers, they told me that was
3 wrong, sir. But this panel can provide me, as the user
4 representative, with the foundation to say here is why this can
5 go forward.

6 I have come here, I have asked this question, and
7 this has been my little project. And I brought this question
8 here because I do not have the wherewithal to rebut these
9 gentlemen by myself, but this panel does. We agree that it is
10 militarily significant and extraordinarily important, but we
11 cannot currently very well go forth with these comments on the
12 table. In addition, the concept of use is critically important
13 because it is line officers that approve these requirements
14 documents.

15 So, we have to go to the Commanding General of
16 Army Training and Doctrine Command for his 4-star signature, and
17 before it goes there, it has to be approved by the Doctrine and
18 Combat Developers at all of the military schools -- Infantry,
19 Armor, Military Police, Engineer, et cetera. So, we need to have
20 the concept of use pretty fairly fleshed out -- fairly well
21 fleshed out. And if it's going to be a total force or high risk,
22 we need help in ascertaining how that's going to be because that
23 did not come to us from the S&T community.

24 I could go on, but I think I've made my point.
25 We've come here for assistance with adjudicating comments in

1 opposition to the candidate.

2 DR. LaFORCE: Kevin?

3 DR. PATRICK: I don't know, Marc, I'm not sure
4 exactly where I stand on this. I'm really very interested in
5 hearing what others have to say.

6 DR. LaFORCE: Pass, no problem.

7 DR. PATRICK: I do want to make one point, or one
8 almost clarification, and it relates to -- it strikes me one of
9 the most impressive bullets here is that a vaccine candidate may
10 be good enough to develop for the sake of what may be achieved
11 short of traditional acquisition requirements, the whole notion
12 of developing -- to pushing forward science and pushing forward
13 potentially an infrastructure that would be capable of developing
14 other vaccine. Am I reading that wrong? Let me pose that as a
15 question, is this not an infrastructure that might, through the
16 process of developing this vaccine, be helpful in responding to
17 the other vaccine needs that we keep hearing about and, thus,
18 that's a good that I think bears emphasis in this discussion. Am
19 I correct in hearing that this infrastructure might, in fact, be
20 helpful in developing other vaccines?

21 DR. LaFORCE: We skipped you Philip. We were
22 going down that side of the table for comments. Why don't we
23 come back to you.

24 DR. LANDRIGAN: Give me a minute to get into the
25 rhythm. We were having a meeting of our subcommittee outside.

1 DR. LaFORCE: Julian?

2 DR. HAYWOOD: I think the last little bit of
3 discussion has put this in perspective in terms of what we're
4 actually being asked to consider and, although I'm not an expert
5 in this area at all, I think the issue is very clear and that we
6 have an obligation to give some advice.

7 DR. LaFORCE: Doug?

8 DR. CAMPBELL: Well, there's a lot of issues, but
9 I think a main issue is that HIV is an incredibly important
10 disease that needs to be stopped, and what do we need to do to
11 get to that point. Private industry is working on developing a
12 vaccine, so why does the military need to come in and set up
13 their own infrastructure to do the same thing? I'm not all that
14 familiar with how effective the military is compared to private
15 industry in developing a vaccine. From what people say, it
16 sounds like they are doing a very good job, but my question is,
17 why do the military have to have their own program over and above
18 what private industry is doing, and if the military can do a
19 better job than private industry, maybe it would be a definite
20 benefit to have the military be involved in making a vaccine.
21 But I guess I'd like to hear why the military should be
22 developing a vaccine over and above private industry.

23 COL. McNEIL: This is a cooperative research
24 undertaking. Industry is unwilling at this point to do this
25 alone. It's a very risky venture to go forward on your own with

1 the development of an HIV vaccine. Their risk underwriters would
2 never agree to do this unless there was a partnership formed with
3 others who could absorb some of the risk, risk meaning
4 contributions that help in the development of the product or the
5 candidate product that aren't costs directly to the company.

6 What we've described here today is a cooperative
7 undertaking with Aventis-Pasteur and Vaxgen, two private industry
8 partners. They are the ones that initially produced the
9 constructions, the candidate vaccines, and we have done the
10 clinical evaluations. For the Phase III trial, they will
11 manufacture the candidate vaccine, we are providing the
12 infrastructure for doing the clinical assessment. We can't
13 manufacture the vaccine at that scale, and they can't absorb the
14 risk of doing the clinical trial without some other partners.

15 A third element to this is the political part for
16 HIV, which is quite different and distinct from other infectious
17 diseases. And in order to get a climate, a political climate,
18 that's acceptable and in fact proactive in supporting these is no
19 small undertaking, and industry has a very difficult time doing
20 that alone. Oftentimes, internationally, an industry shows up,
21 they are looked at quite skeptically. It's approached as a
22 partnership that includes multinational organizations, U.S.
23 Government, foreign governments, industries of health, private
24 industry, UNAs, which this is, it works. Anything short of that
25 doesn't work very well.

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1 So, we're not doing it alone. We're not doing it
2 better. We are doing it in partnership.

3 COL. DINIEGA: I just want to make a comment, and
4 John probably can talk to it a little bit better. There have
5 been success stories with cooperative research agreements that
6 have led to products, and hepatitis-B is one of them. That was
7 developed in the U.S. military and taken to licensure by one of
8 the other pharmaceutical companies, and done in conjunction with
9 the military.

10 DR. LaFORCE: John.

11 DR. HERBOLD: My experience would say that the
12 Board should look to the question of are there military unique
13 aspects of vaccine development that the military should focus on,
14 or only the military would focus on, as you go down this R&D
15 trail.

16 One example that I would cite about military-
17 specific vaccine development would be on focusing on vaccines
18 that would prevent infection contrasted with vaccines that would
19 reduce viral load in those already infected. And if the
20 technology broke towards -- that you could do some quick
21 development of things that would reduce viral load in those
22 already infected, I think industry and National Institutes of
23 Health would go down that trail and not remain focused on vaccine
24 development of a product that would prevent infection. And I
25 think in the operational setting, that prevention of infection

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1 would be the military-unique focus for the Department of Defense.

2 The argument that the military can do it better than Chrysler or
3 Ford doesn't hold. It has to be a military-relevant issue, and
4 we could argue about the military relevance of developing a
5 vaccine that prevents infection. I think it's a substantial risk
6 to forces that are deployed, but I think the Board needs to focus
7 on helping answer that single question.

8 DR. LaFORCE: Bill?

9 DR. BERG: I think there are a number of points
10 I'd like to make. I think, as Adm. Zimble said, the secret of
11 success with the Board is asking the right questions, and I
12 applaud Col. Scott's restating of his questions, I think that
13 clarified it significantly.

14 Secondly, I think it's highly appropriate for this
15 Board -- in fact, it's one of its historical obligations to do
16 things like look at the ORD and rewrite it as necessary. And
17 speaking just for myself, I think making the changes along the
18 line that have been suggested here is favorable, or at least I
19 would be in favor of it.

20 The third point I think I'd like to make is, when
21 we talk about a military important disease, just what are we
22 talking about? and I'm going to say this a little bit tongue-in-
23 cheek, but if Col. McNeil and Gen. Parker painted this as any
24 blacker plague, I think we ought to insist on a 99-percent
25 efficacy.

1 I find it hard to think of this as military
2 important when you think that the role of the military is combat,
3 and this is not an infection that affects combat. Only 300
4 people get infected, only 10 percent of those get infected
5 overseas. Most people have an early onset infection that is a
6 relatively mild viral like illness, and then die, if they die,
7 years later. By the time they are back from Sierra Leone or
8 Bosnia or Herzegovina or wherever.

9 So, if we say the role of the military is combat,
10 I don't think you can argue much that this is a militarily
11 relevant vaccine. I also don't see it protecting the walking
12 blood bank. I mean, the threshold is 90 percent. The argument
13 here has been for 80 percent efficacy. Many of the speakers have
14 said, "Oh, it ought to be as low as 60 percent". You're going to
15 get a false sense of security if I say, "Well, I can take blood
16 from you because you got the vaccine".

17 I think the argument, though, is that there are
18 numerous vaccines -- looking at the Tier I vaccine for biological
19 warfare -- for which we do not have a good vaccine and for which
20 industry is not likely to be interested. And I think the
21 spinoffs of this whole project are where the big payoffs lie and
22 why the Board should be endorsing this project.

23 DR. LaFORCE: Thank you.

24 DR. SHANAHAN: I'll have to say this has been, to
25 quote a baseball player, "deja vu all over again". I had the

1 good fortune of being with this command for most of my military
2 career, and I can remember when these questions first came up.
3 It is my recollection, Dr. Moore, that it came directly from
4 Congress initially. And we went through all of these discussions
5 before, and I have to say I was on the other side of the table in
6 terms of whether I supported it or not because, in a large part,
7 even though the initial funding had come from Congress, the
8 subsequent funding is going to come out of the command's budget,
9 and I was trying to keep a laboratory alive that was getting
10 strangled by budget.

11 But these questions did come up during that period
12 of time, all these questions I've heard before. In my view,
13 there were a number of people within the Medical Corps and
14 outside the Medical Services Corps, who had much more of a long-
15 range view of the subject than I did at the time, and some of the
16 other people who were in opposition to HIV research in the
17 military, including some of these predictions about what might
18 happen to HIV in the future. Fifteen years later, we can see
19 that those predictions, many of them, were fairly accurate.

20 I think it is within our purview to look at this
21 and consider whether it's militarily relevant. I think my own
22 opinion is that there is a fairly high degree of military
23 relevance. Is it exclusively military? No. And I think that's
24 going to be part of the question, too, that Dr. Berg is raising,
25 to what degree is it militarily relevant, and to what degree

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1 should it be supported by the military. Initially, it was a
2 congressional decision, and certainly long before HIV, Walter
3 Reed and this Institution have been involved with vaccine
4 development over a long, long period of time.

5 So, I think that we certainly have a lot of
6 questions to ask about that, but there certainly is a degree of
7 relevance to the military.

8 The other issue is that I find that what Col.
9 Scott brought up, much of the kinds of comments he's getting from
10 commands tend to be rather naive in my view. And I think that
11 there may be an issue here of education as well.

12 I know that this has been well sold within the
13 Medical Department, but I haven't seen good evidence that field
14 commanders have been really made aware of the relevance of this
15 situation. That would be one suggestion on my part, is that
16 there may be some more that can be done in that regard based upon
17 the comments that I've heard.

18 And, of course, the other thing that strikes me is
19 the idea of having very hard, fixed requirements for this
20 vaccine. I know there are certain practical considerations, but
21 given what we have now, which is essentially nothing, even if you
22 get a vaccine that's 60-percent efficacious, if it's also safe
23 and can be used, it's 60 percent better than what we have right
24 now, so I'm not sure that should be excluded.

25 The other difficulty in setting those very hard

1 objectives or guidelines is that you run the danger -- and I've
2 seen this happen in many research programs -- of losing the
3 program all together if you make your objectives too high. I
4 mean, not just the particular drug you're working on, the
5 particular object you're working on, but lose the whole program
6 and thrust. So, I think that's another consideration in this
7 program.

8 DR. LaFORCE: Thank you. Robert?

9 DR. SHOPE: I very much believe that this is a
10 military problem, which would answer Gen. Parker's question. I
11 guess I wouldn't have selected adenovirus as the unimportant
12 comparison to make because it's also, I think, a very important
13 problem for the military, not because it kills people but because
14 it disables people.

15 I'm concerned about the slide that has the program
16 objective on it. As the program objective, it says "Develop a
17 field and FDA-approved stable vaccine to prevent illness". I
18 think that what they are outlining to us is a vaccine to prevent
19 infection, not a vaccine to prevent illness, and that there's
20 basic inconsistency, and I think it's okay for the military to be
21 trying to develop a vaccine to prevent infection. In fact, as
22 someone has just pointed out, that's one thing that the military
23 can do that some of the NIH programs are not particularly aimed
24 at.

25 So, I would give this a vote of confidence, but

1 make sure that we understand what it is that the military is
2 trying to develop.

3 DR. LaFORCE: Thank you. Rosie?

4 DR. SOKAS: I would also give this a vote of
5 confidence. I think it is as important as preventing heat stroke
6 among new recruits. I mean, I think there are things that don't
7 kill people in great numbers, but that are nevertheless important
8 for military readiness.

9 I also am very persuaded by the argument that if
10 the south of Africa destabilizes and if the newly emerging states
11 in the former Soviet Union destabilize, that that's going to have
12 implications down the road for deployment that are really going
13 to be difficult, and that for all of those reasons this is an
14 appropriate military issue.

15 I also have to say that it kind of appeals to me
16 the fact that there's a David and a Goliath, and here is NIH
17 getting lots of money and here is the military coming up with an
18 effective vaccine way in advance, it looks like. This may speak
19 against my next question, which is, has the military tried to get
20 any money from NIH through a Memorandum of Understanding or -- on
21 the one hand, I think competition is a good thing and we saw that
22 on the human genome project. On the other hand, if they have too
23 much money and they don't quite know what to do with it, this
24 seems like it might be an appropriate place to use it. I don't
25 know if that's been considered or discussed, or if that's just

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1 completely off the wall.

2 DR. LaFORCE: Philip?

3 DR. LANDRIGAN: I think any fatal infection that
4 involved 323 people last year is something that has to be taken
5 seriously. Even if I accept the data that only 10 percent got it
6 overseas and even if maybe all 323 got it doing stuff they
7 shouldn't have been doing, the fact is that 323 members of our
8 military were infected with a disease which is ultimately going
9 to prove fatal. I think that that's an issue that the military
10 has to take very seriously. That's for the present.

11 I think for the future, I think the geopolitical
12 argument is an interesting one that the General brought up and
13 that Rosie just reiterated, but I think there's another future to
14 mention, and this is something that I'm fairly keenly aware of
15 because I'm still in the Navy Reserves and I'm assigned to a
16 Fleet Hospital, and a Fleet Hospital is a deployable tent
17 hospital, and increasingly it seems to be that our mission is not
18 to go places to fight wars, although those will certainly happen,
19 but equally as much to go places to do various kinds of missions
20 other than war, where we're rendering various kinds of
21 peacekeeping assistance or providing care to civilian
22 populations, and it seems to me that as units like mine run the
23 risk of getting deployed to places like sub-Saharan Africa or
24 Southeast Asia, where there's a 20-30 percent prevalence of HIV
25 infection among some of the patient populations they'll be

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1 treating, I would feel much more comforted as a senior physician
2 of a Fleet Hospital, if I knew my people were protected against
3 this highly prevalent infection. Just as I would take malaria
4 prophylaxis going into a malaria zone, it would be awfully nice
5 to be able to take prophylaxis against HIV before going into a
6 zone that was a hot zone for HIV. And I don't know if that point
7 has been brought out before. I think Dr. McNeil made the point
8 about heavy -- what did you call it, a "heavy blood zone", like
9 the -- you used some term of art which resonated with me.

10 COL. MCNEIL: Casualties in high prevalence areas.

11 DR. LANDRIGAN: Lots of blood, yeah. So that
12 struck me. I also share the view that a couple of people have
13 expressed, that I don't think the bar should be set too high. I
14 think that if the bar is set unrealistically high and the program
15 fails to meet those goals, that could be the kiss of death for
16 the program. I think that a simple goal of reducing viral load
17 is probably the most important, and whether it's one shot or
18 three or four, whether the shelf life is six months or five
19 years, those are secondary considerations. The important thing,
20 in my view, is to reduce the infection. And I'll stop there.

21 DR. LaFORCE: My comments mirror pretty much what
22 some of you have already said. In terms of the first -- or the
23 response to the question that had to do in terms of the USAMMDA
24 performance requirements, I would favor making a specific
25 recommendation that for USAMMDA performance requirements, the

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1 issue of preventing virus transmission is acceptable. Ability to
2 distinguish between infection and receipt of vaccine would be
3 another central criterion. The rest of them are out.

4 COL. McNEIL: Do you mean prevention of infection
5 versus prevention of transmission because prevention of
6 transmission will be impossible to prove.

7 DR. LaFORCE: However.

8 COL. McNEIL: Well, there's a huge difference
9 between preventing infection and demonstrating prevention of
10 transmission.

11 DR. LaFORCE: Okay. What you're talking about in
12 terms of that particular distinction is this is a difficulty in
13 terms of a research study, is that not correct?

14 COL. McNEIL: I think the primary objective of
15 showing that an individual is protected and they have sterilized
16 immunity that they don't get infected, we can demonstrate that.
17 But once immunized, if they become infected, demonstrating that
18 they are not capable of secondary transmission --

19 DR. LaFORCE: Oh, I understand.

20 COL. McNEIL: -- is something that cannot be done
21 in a Phase III study.

22 DR. LaFORCE: I would defer to the smart
23 virologists.

24 DR. SHOPE: You meant to prevent infection.

25 DR. LaFORCE: That's correct.

1 (Simultaneous discussion.)

2 COL. McNEIL: It's written now to prevent illness.

3 DR. LaFORCE: I think what you want to prevent is
4 HIV infection. How that gets prevented, whether it's cytotoxic
5 T-cells or whether it's antibodies that's taking care of it, I
6 mean --

7 DR. HERBOLD: But that's Dr. Shope's point, and
8 that's not what they said.

9 COL. DINIEGA: That really doesn't matter because
10 what matters is the ORD. The ORD is the issue here. We have two
11 processes that are banging heads with each other -- FDA
12 requirements and the scientific requirements versus the
13 requirements of an ORD which is part of the bureaucratic process
14 for taking user requirements and make them into a device and
15 putting them out in the field. That's a bureaucratic requirement,
16 and it's banging heads with the scientific knowledge and
17 requirements. You know, John outlined it very clearly on there
18 as along with the creative partners, what their objectives were
19 in the vaccine. They are very different from what the
20 requirements in the ORD would be.

21 COL. BRADSHAW: I have to comment. As one of the
22 people that Dr. Scott had to deal with, I think, in commenting on
23 the ORD, I would have to confess maybe some relative naivete in
24 terms of crafting an ORD for new vaccine development. On the
25 other hand, if you ask me what I want and need in a vaccine, I'm

1 speaking from the perspective of kind of the anthrax wars in the
2 last several years, and when you look at a 6-shot vaccine regimen
3 that gives people a whole heck of a lot of opportunity to
4 temporally associate an adverse event or outcome with a shot, and
5 it's a vaccine that they're not sure they really need, to me, a
6 lot of people in the military are going to think, "I'm not sure I
7 really need the HIV vaccine, why are they giving me four or five
8 more shots?"

9 And so when I responded -- and I think back of the
10 acceptance we had with the hepatitis-A vaccine which was a 2-shot
11 regimen, and compared that to what we had when we tried to roll
12 out anthrax vaccine, to me the idea was two shots. Now, it's
13 probably too much to ask for to have a Yellow Fever vaccine as
14 one shot and then to get it ten years later, and maybe what I'm
15 asking for is the middle ground here, is to get something that's
16 kind of realistic, but we have to do the risk communication for
17 these things, and it's getting harder and harder to get people to
18 accept new vaccines, especially if we make them mandatory for the
19 entire force, as part of readiness, and we're not doing it risk-
20 based. And so that's the perspective that I, as at least one
21 commentator on this ORD, was coming from when I suggested that
22 maybe we should have the efficacy up towards 80-90 percent. I
23 mean, we had a hard time selling anthrax vaccine with an efficacy
24 of 92 to 95 percent.

25 And so those are the perspectives that I was

1 coming from, at least, as one of the commentators that was having
2 to deal with it. And it was not intended to be a poison pill to
3 shoot down the program. That certainly was not my intent.

4 DR. LaFORCE: Yes?

5 COL. McNEIL: First, to address what Col. Diniega
6 said about looking at the ORD itself. It says efficacy, and
7 we're debating here about what we mean by efficacy, prevention of
8 infection or prevention of disease. So I think it is important
9 that we're clear about what we mean by efficacy because the ORD
10 just says efficacy, it doesn't say what it means by that.

11 The USAMMDA slide does say disease or studies
12 designed to look at prevention of infection, and so I think I can
13 make sure that USAMMDA is concordant with us on stating that it's
14 infection as the primary measure.

15 The other thing I think that would be helpful is
16 for these performance requirements, it's fine to have them listed
17 with thresholds and objectives, but when you make them key
18 performance parameters, then I think that's where we have a
19 little bit of problem. You're making it much more difficult then
20 to have some leeway with a vaccine that maybe doesn't strictly
21 meet your thresholds, and we're going to have a really hard time
22 buying it. The rest of the world is going to use it if it is 60-
23 70 percent efficacious against infection, that's going to be a
24 grand slam homerun.

25 COL. BRADSHAW: I'm okay with flexibility.

1 DR. LaFORCE: I agree with you completely, if the
2 studies are done in such a way that a single dose or two doses, I
3 don't think anybody would disagree with you at all.

4 The only point I was trying to make is this issue
5 of key parameters. I think the parameters, as outlined, that's
6 all fine, but to me the issue is what are you going to put as a
7 key parameter because a key parameter, to me, is a deal-breaker.

8 That's the one if you can't meet, it's a deal-breaker. And for
9 me, there are only two deal-breakers, and that's the issue of
10 infection and, secondly, the issue of you've got to be able to
11 distinguish if there's an immune response in an individual from
12 vaccine, you've got to have an absolutely solid way of saying is
13 this vaccine-induced or is this infection. I think that's an
14 ethical obligation to the individual that you're immunizing.

15 So, for me, the list of performance requirements
16 that are here could be longer, could be shorter, I'm not smart
17 enough to be able to say which it is, and I think individuals are
18 going to argue about whether -- is 3-dose too much, 2-dose too
19 much, or whatever -- but to me, the discussions that I think the
20 Board has to have are what are the deal-breakers because if the
21 deal-breakers are real deal-breakers, then that's the end. It's
22 finished.

23 DR. MOORE: The comment you just made about
24 distinguishing between infection and vaccine used a lot of time
25 in our early discussions about whether we would pursue this

1 vaccine initiative, and it had to do, among other things, with
2 the selection of a test population, individuals that were
3 involved in risky behaviors that might confuse the issue of how
4 we would interpret whether or not this was a natural infection or
5 vaccine-induced immunity. So, that's a key issue that has to be
6 addressed, and John and the group have thought about that.

7 COL. ENGLER: I just wanted to make two comments.

8 One is, serving on the Future Vaccine Subcommittee of the
9 National Vaccine Advisory Committee, the concern about
10 development of vaccines for which there is not an immediate math
11 of profit motivation and how to subsidize this is a national
12 concern. So, I would say that this program, you know, is a vital
13 template example of a partnering between industry and spreading
14 out the risk cost, particularly of the clinical trials, and in
15 that regard there's a lot of concern that we don't have enough
16 examples like this so that there will be a lot of orphan vaccines
17 and potential technology, and without the Bill Gates Foundation
18 infusing money into TB vaccine, the comment was made, you know,
19 we'd never see one, but we can't depend that there's always going
20 to be a Bill Gates Foundation. So, in that regard, I would say
21 that this is a program that deserves unanimous support. But I
22 would just bet you, echoing Col. Bradshaw, that whatever the AFEB
23 recommendation is, that you segregate out the value of the
24 vaccine development and, yes, it has military relevance, like
25 it's good to have a Lime vaccine, but this Board decided not to

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1 make it a hundred percent required vaccine because balancing the
2 cost implementation and the commanders, when they screamed "we
3 can't do it", it's not an education problem, it's that -- you
4 know, we conservatively estimated that one shot to 2.1 million
5 people costs at least \$52 million to deliver, and probably a
6 helluva lot more, and that the acceptability -- we're having
7 ethnic paranoia about anthrax, and there is a great belief,
8 particularly in the Muslim community, that vaccines spreads AIDS
9 so that if we have a problem now with people opting out of the
10 military because of the anthrax vaccine requirement, I would just
11 beg you, beg you, beg you, that whatever vaccine develops, that
12 you phase in initially in a very selective and potentially
13 voluntary way because you're going to break the back of the
14 system. It just can't sustain it and support it, and the
15 education complexities -- the NIH discussion on public paranoia
16 about any DNA-based vaccines, about, you know, concern of future
17 cancer risks, et cetera, et cetera, we desperately need an HIV
18 vaccine, but I'm telling you, in the American public, to phase it
19 in is going to be a very, very challenging and -- it just won't
20 work. So, if you could separate out "yes, it's important", it's
21 militarily relevant, world-stabilizing, saving continents, and
22 the option that it's available is very important for our overall
23 national defense and protection of people, but don't make the
24 statement now and commit yourself to something because you'll
25 rile the opposition by saying any implication that you're saying

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1 it's going to be a total force insertion required vaccine.

2 DR. LaFORCE: We sometimes end up in the curious
3 position of recommending that we develop a fully effective
4 vaccine to be used in everyone else except the military. David?

5 DR. ATKINS: I think one of the things that's
6 confusing to me is that this is sort of at the intersection of
7 research and procurement. So, clearly, what we would support as
8 going ahead as an important step onto getting what we might
9 ultimately want is being phrased in the ORD as kind of defining
10 what we need, and I assume it's tied to the process. So I think
11 it's perfectly reasonable to say that what we would like as a
12 vaccine that we could actually usefully implement would be
13 something that would have the kind of characteristics Dr.
14 Bradshaw talked about. And I don't know if starting a Phase III
15 trial requires that you have something that meets all those
16 requirements before it can go into Phase III -- I mean, it would
17 seem that the way vaccine is developed is you find out what works
18 and then you make it more feasible and more effective. So, if
19 there's a way to sort of emphasize that fact and, clearly, it's
20 the key performance parameters that really become binding on what
21 can go forward to a Phase III trial. I mean, I'm certainly in
22 agreement with what everyone else said, that we should be setting
23 the bar that high. At the same time, I'm comfortable with
24 supporting the fact that these issues of feasibility need to be
25 taken into account in terms of what we ultimately want.

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1 DR. LaFORCE: Ken?

2 CAPT. SCHOR: I would just like to say must the
3 ORD be written with the target population only the active duty?
4 If you write the ORD as if only the military is going to get this
5 vaccine, which is the undercutting current here, you get a lot of
6 very interesting biases in the ORD. But if we are writing the
7 ORD to develop a vaccine for humanity, it might say very
8 different things. And I think that's biasing the process
9 tremendously, and risking the development of an important vaccine
10 that has global implications, let alone national security
11 implications, and I would ask that perhaps it would be
12 appropriate for the Board to say -- you know, the target
13 population is not just the military and that it's more important
14 to emphasize what would be general scientific operating
15 characteristics of the vaccine than acquisition characteristics.
16 It can be sold in an acquisition and economic model.

17 DR. LaFORCE: May I just ask the question as to
18 whether that would be acceptable? I don't think that would be
19 acceptable because they would sort of look at that and say
20 "stop".

21 LtCOL. SCOTT: But if it was outside the Army
22 acquisition system, no problem. But having been stuck into the
23 Army acquisition system --

24 COL. BRADSHAW: Although I would say if you're
25 looking at optimum vaccine characteristics, even there, when

1 we're thinking about the ultimate population -- say, the African
2 subcontinent, or continent rather -- that a 2-shot regimen is
3 certainly going to be a lot easier to operationalize in that
4 setting than a 4-shot regimen.

5 DR. LaFORCE: No question, except that -- and I
6 spent a fair amount of my time working there, and the amount of
7 horror that is there right now is such that if there were six
8 doses, that you wouldn't have any trouble getting rid of your
9 vaccine, I can tell you that right now. Ben?

10 COL. DINIEGA: Just a little historical reminder
11 that there have been large Phase III trials that have been
12 undertaken for potential vaccines in the military that have not
13 gone through, they failed, one of them being a huge effort for
14 Minengi-B, and it didn't meet one of the key parameters, like you
15 said. And so the decision at the Milestone Decision Review was
16 to terminate. The Korean Hemorrhagic Fever vaccine that they
17 were working on was also terminated because it didn't meet a key
18 parameter. So the emphasis on the key parameters, like you said,
19 is very critical.

20 The other thing is, the way this is going as far
21 as the process for this vaccine sort of takes it out of the norm
22 for funding in more than just a congressional interest and
23 congressionally-directed dollars and supplements. Usually there
24 is a big fight for advanced development dollars, and it sounds as
25 if this comes with almost a guaranteed advanced development

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1 funding, whether it be from the military or with a partner. So,
2 it is a little bit different.

3 Usually, at the advanced development stage, there
4 is some commitment to start putting money aside in future budgets
5 for acquisition, and I'm sure this would not happen, Brian, until
6 the results of the Phase III is known. There's no real
7 commitment other than the funding for Phase III trials at this
8 point. There's no commitment beyond that until they see the
9 results of the Phase III.

10 There is a risk -- there is a risk, and it's been
11 seen already for second generation vaccine development in that
12 originally anthrax has a licensed vaccine and, as such, it was
13 taken out of the research program because it's already a licensed
14 vaccine that's available against a BW agent, and it was not part
15 of the JVAC program. But because of the interest in a new
16 generation vaccine that would be easier to administer with less
17 side effects, it's come back into the research. Otherwise, it
18 would not have been funded into the research arena. Once there
19 is a licensed product, they move on to the next, so there's a
20 little bit of a risk there. But I agree that this is a first
21 generation vaccine, and we have been using our prevention
22 methods, behavioral methodology, and our screen methodology is
23 the only way to prevent disease in the military. And I think, if
24 I remember correctly, until the mid '80s it was only because we
25 didn't have any other chemoprophylaxis or vaccines in place.

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1 DR. SHANAHAN: I really have two comments which
2 are more cautions. One is, I feel pretty strongly that whatever
3 we end up doing, that at least we don't support putting third
4 generation requirements on a first generation vaccine, and I'm
5 not exactly sure how we'll come down on these particular issues,
6 but I don't think this Board should be establishing those kinds
7 of requirements.

8 The second thing I'd like to make is really to
9 support Col. Engler's comments, and that is although I believe
10 that there is a military relevance to the vaccine, I have a
11 strong caution, at least in my own mind, about getting into a
12 situation like the Manhattan Project where you have a lot of
13 scientists who are participating in building this object just as
14 a scientific project without really any long-term thought about
15 how it was going to be applied, and many people afterwards had
16 certain regrets about that quite famously and obviously.

17 I think we run the same risk with these kinds of
18 vaccines as well. I'm not saying that we shouldn't approach it,
19 but I think we should take a long-term view, as I think Dr. Moore
20 has also brought up, of the ethics of the situation and how it is
21 going to be applied. Within the minds of people in the United
22 States, this is not like preventing the flu, and we've got to
23 consider those issues and about how this vaccine is going to be
24 applied, whether it's mandatory for all or how it's going to be
25 used.

1 I'm not sure we have to give specific
2 recommendations in that particular area, but I think we should at
3 least amongst ourselves have addressed those issues.

4 DR. LaFORCE: Let me go back to the issue of the
5 military relevance as far as the vaccine is concerned. This was
6 just my first point. The second one had to do with the military
7 relevance, and I think your point is absolutely correct, Philip
8 and Dennis, that the likelihood that there's going to be
9 deployments that are going to be in Africa over the next ten
10 years is virtually 100 percent, I would predict.

11 I would also predict that it would be imprudent
12 not to prepare for that. So that means there are going to be X-
13 number of deployed American forces that are going to be in very
14 high end domicity rates of HIV infection, with all the other
15 attendant problems that are there, that are part of that
16 deployment exercise.

17 So, therefore, I think it's probably going to be
18 mandatory, if there is an effective vaccine, to ensure that these
19 troops that are deployed in these areas are at least protected.
20 That's in contradistinction to saying "I know that every single
21 military person will have to have this particular vaccine". I
22 don't know what the answer to that is going to be. That's going
23 to get deliberated and argued and decisions are going to be made.

24 But I think any reasonable person would say that a part of a
25 deployment preventive medicine issue is very likely to be

1 addressing or making sure that those troops are immunized against
2 HIV.

3 So, I would say just in that parameter, just
4 following that particular parameter, there's an absolute
5 indication in terms of military relevance for this particular
6 antigen, even if you sort of completely ignore the notion that
7 some people have argued that it really is going to be a universal
8 vaccine for all adolescents. So, I would argue those particular
9 lines, which I actually feel pretty comfortable in terms of that.

10 Now, with that --

11 DR. LANDRIGAN: It has the advantage of focus.

12 DR. LaFORCE: Oh, yes, it has the advantage of
13 focus. The other thing, it has the advantage of the Clinton
14 Executive Order, which I think was very, very specific about
15 ensuring that if American military are going to go into harm's
16 way, there was a fundamental obligation to ensuring that they
17 were as protected as you possibly could make them against events
18 that were going to occur during the course of that deployment,
19 and that would be, at least as far as I'm concerned, HIV
20 infection.

21 So, with that parameter in mind, the issue of --
22 and also with one other parameter which hasn't been, I don't
23 think, emphasized enough, although Ben mentioned it before -- was
24 the track record of the U.S. military in terms of vaccine
25 development -- you know, hepatitis-A -- Ben mentioned hepatitis-

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1 B, hepatitis-A -- all of the other -- you know, the Japanese
2 encephalitis randomized control trials that Charlie Hoch did in
3 Thailand -- I mean, there's a whole litany of absolutely superb
4 work that has fundamentally changed public health parameters
5 globally.

6 So, I think that when we talk about this -- you
7 know, Walter Reed or whomever in the military, or whether it's
8 NAMRIID -- you really start with a certain level of excellence
9 that's a little bit different than some sort of cottage industry.

10 This has been a central component of a lot of military medical
11 research.

12 And having said that -- and we were talking at
13 dinner last night a little bit about this -- is that the
14 military, particularly Walter Reed, started off way ahead of
15 everybody in terms of this issue, in terms of HIV infection. I'm
16 not a good enough retrovirologist to say are they still out in
17 front, are they behind, or is somebody tied with them, I just
18 don't know. And I think that is begging the question, the main
19 thing is, the research activities appear to be absolutely
20 perfectly reasonable. They have a study site in Thailand that is
21 likely to be a study site that is going to be a reasonable study
22 site in terms of being able to at least answer one of the
23 cardinal characteristics of "is this going to work or not". So,
24 I find actually a lot of arguments both in terms of military
25 necessity and also a certain track record within the

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1 establishment that leans me quite easily towards supporting this
2 particular initiative, not as a global recommendation for it, but
3 because I think that's going to come much, much later, Dana. I
4 think that's going to come much later.

5 DR. ALEXANDER: The reason I like your approach is
6 it's appealing on the political level, it's much more palatable.

7 It diffuses the arguments that come in about the behavior of
8 soldiers and what they should and should not be doing. You're
9 not getting into that with your approach, you are bypassing it
10 entirely, and I think that legitimizes the decision in a way that
11 the other arguments we've made really didn't. Much more
12 appealing.

13 DR. LaFORCE: Bill.

14 DR. BERG: I agree that this is a vaccine that's
15 important to the military, but I think we also need to keep in
16 focus in terms of importance to what military. If we're sending
17 troops into Africa, obviously the medical personnel are at high
18 risk because they're going to be dealing with the refugees and
19 other people there.

20 Infantry troops, Marine troops, they may be at
21 some risk. They may be carrying in someone who has been shot up,
22 something like this. What's the risk of a tank driver? What's
23 the risk of a helicopter pilot?

24 DR. LaFORCE: Depends on what he does on Saturday
25 nights. You know, again, it's not the risk -- it's all the risk,

1 Bill.

2 DR. BERG: I understand that, but the risk is with
3 deployment overseas, it goes down in combat. And the risk was
4 very low in Saudi Arabia because of very strict rules about
5 fraternization.

6 DR. LaFORCE: I think, from my experience in Saudi
7 Arabia, my experience in South Africa, those are two totally
8 different environments in terms of the issue of fraternization.

9 DR. ATKINS: What is the military policy about
10 hepatitis-B immunization in deployed troops?

11 DR. LaFORCE: It's a universal antigen, is it not?
12 (Simultaneous discussion.)

13 COL. DINIEGA: It's required for all health care
14 workers, that's the policy.

15 DR. ATKINS: How about for deployed --

16 COL. DINIEGA: And to certain high-risk areas
17 because it's required for the Army to Korea, and the Navy may
18 have some other requirements.

19 CAPT. SCHOR: We have not won funding -- despite
20 our best efforts, we have not won funding for Far East deployers
21 in the Marine Corps.

22 DR. LaFORCE: To get hepatitis-B?

23 CAPT. SCHOR: Yet.

24 COL. DINIEGA: But the Navy would like to go to
25 anybody deployed to the Far East.

1 DR. LaFORCE: Because that would be utterly
2 consistent with what we're talking about. I mean, those are
3 prevalence rates or carrier rates of 4 to 10 percent.

4 DR. PATRICK: Marc, can I say I think you've done
5 an excellent job focusing the issue and bringing it down in what
6 I would consider dividing the issue because I think I was sort of
7 lumping the issue in my mind, and I think you've really
8 crystallized it in my mind.

9 But I would offer another potential key
10 performance parameter to have us thinking about -- and it may not
11 be in this venue -- but what I'm hearing are issues that relate
12 to acceptability of these vaccines to users, and it's both the
13 deployers, the clinicians who have to put them into place or the
14 systems that have to put them into place, and it's the docs, the
15 nurses, the other people that are doing that, and then the
16 endusers.

17 And I would submit that there's a legitimate line
18 of research here that needs to be funded, just like this kind of
19 research. I mean, it's not enough to develop a vaccine, we need
20 to be looking at how can we move and change systems, and how can
21 we make these things acceptable. How do we basically make these
22 whole or demand kinds of issues rather than push kinds of issues.

23 And just as smoking a long time ago was considered a fact of
24 life and we never thought that there were behavioral issues that
25 could be focused upon for research, I would think that this is a

1 legitimate line of research, and I'm not sure whose
2 responsibility it is to fund that, but certainly I'm hearing
3 there's push-back within these systems, and so some measurable
4 percentage of the research effort should be how to change these
5 into make these vaccines acceptable.

6 COL. ENGLER: I just want to make a comment that
7 one of the focuses of the VHC collaboration is to do -- to be a
8 platform on which to further explore the issue of attitudes and
9 beliefs and what are effective ways to reach people where they
10 live in credible ways, and also in the context of ethnicity, and
11 we are at the starting gate. We are, you know, pre-Phase I. And
12 there has not been -- several years ago when I first started
13 coming to this thing, I said, you know, there's been so little
14 resourcing on the clinical delivery side and quality improvement,
15 and I said you can have warehouses full of wonderful vaccines,
16 but the anthrax lesson alone, and also -- not just anthrax, but
17 CDC is reeling with the vaccine NOFORC. It's a powerful wind,
18 it's growing, it's ever more organized, and just saying here's
19 the data, it's safe and effective, hasn't worked and will not
20 work.

21 DR. PATRICK: Absolutely, and this is very similar
22 to what was faced in the clinical community and moved us from
23 compliance to adherence, which is really more that partnership
24 sort of thing. I mean, it's very much part of the same thing
25 and, again, I think takes measurable effort to move down this

1 road. Hopefully we will make some progress.

2 DR. LaFORCE: Rick.

3 LtCOL. RIDDLE: Actually, if you will look in your
4 materials at Tab 7, we have some sample ORDs in there. One of
5 the key performance parameters for the next generation anthrax
6 vaccine is the system education materials, which includes risk
7 communication, leadership, public -- those kinds of things. So,
8 those work risks are in this ORD. I didn't see them in the HIV
9 ORD.

10 LtCOL. SCOTT: They are in there.

11 COL. DINIEGA: There was a commitment from the
12 AMMED Center and School a year and a half ago, that they would
13 add the systems training and education plans in all of the
14 medical acquisitions programs.

15 DR. LaFORCE: I would say along those lines,
16 though, the news isn't all bad. Those of us who are old enough
17 to remember what coverage was like with influenza vaccine for
18 over-65s back about 15 to 20 years ago when we had a national
19 average that was somewhere around 28 percent or 30 percent. I
20 mean, that number has now gotten to -- what is it, Dave -- it's
21 above 60 percent now? We're above 60 percent. That's been a
22 see-change that has occurred as a result of education, as a
23 result of -- I don't know -- promotion. The CDC has gotten
24 behind it, the ACP. So, it's not all bad news. We can make
25 progress, and I think there's been a lot of progress that's been

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1 made with influenza and pneumococcal vaccines, just as examples.

2

3 This is a great discussion, keep going.

4 COL. WITHERS: I want to make several small
5 points. I think the Board should not forget to focus on the
6 questions. Discussion is great, but don't forget to focus on the
7 questions. The General and the Admiral are correct, you should
8 decide in your minds whether it's militarily relevant or not. I
9 feel it's in the middle somewhere between MS and malaria. That's
10 my answer. But, you know, like Dr. Sokas pointed out, we worry
11 about heat injury and, sure, that's a combat detractor, but it's
12 mainly a training detractor. So, yes, we should worry about this
13 as much as we worry about heat injury or motor vehicle accidents
14 in the U.S. And the question should be answered specifically
15 and, of course, the Board can add philosophy as you like.

16 DR. LaFORCE: No, no, no. I think the part of
17 honing down to an answer, though, is really sort of letting it
18 float out a little bit and then seeing -- tonight we're going to
19 think about it and see if we can hone down --

20 COL. WITHERS: I'm not being critical, Dr.
21 LaForce.

22 DR. LaFORCE: No, no.

23 COL. WITHERS: And another thing is, it really is
24 a political -- and I asked my question earlier when Gen. Parker
25 was here because I wanted you all to know that it's sort of a

1 minefield of an area, and the Board is, for some reason I'm not
2 fully aware -- I'm not certain in my mind I know yet why this
3 issue is being resolved this way and no other ORD has ever been
4 resolved this way before. I haven't had that answered yet, to my
5 satisfaction. I'll just go with that answer, I guess.

6 DR. LaFORCE: It doesn't have anything to do with
7 the innate brilliance of the Board?

8 COL. WITHERS: I don't think so.

9 (Laughter.)

10 DR. LaFORCE: I'm only kidding.

11 COL. WITHERS: You know, Gen. Parker's answer was
12 because it's -- because the military relevance has been
13 questioned, that's his answer. I think another answer is the
14 money came without being requested. I think the cart was put
15 before the horse, from the military's viewpoint. That's my
16 answer, but it may not be the right one. My conclusion is
17 because the cart was put before the horse and said "here, run
18 with it".

19 DR. MOORE: Can I comment on that, Marc?

20 DR. LaFORCE: Yes, of course.

21 DR. MOORE: You may recall, Ben, that Ted Stevens
22 was the fellow who appropriated or got his committee to
23 appropriate the \$50 million that came to MRMD in the first place,
24 for HIV research because nobody in the Army wanted to touch it.

25 COL. WITHERS: It was not requested, am I right,

1 sir?

2 DR. MOORE: No, no. Ted Stevens came up with that
3 on his own.

4 DR. SHOPE: Just one perhaps minor comment. You
5 suggested two key parameters, performance parameters. I'm
6 wondering whether you would also include a third one, the
7 approval by U.S. FDA because I think I would.

8 COL. DINIEGA: It's a given.

9 DR. LaFORCE: What was the problem with approval
10 by FDA? There is no problem, right?

11 COL. DINIEGA: There shouldn't be because if it's
12 not approved, it can only be given under an IND.

13 DR. SHOPE: If it's not approved, it will probably
14 be because it's not safe. We wouldn't want it to be used if it's
15 not safe.

16 COL. DINIEGA: No, that's not true. We have many
17 IND vaccines that are not approved because no commercial maker or
18 manufacturer will take it to licensure because they won't make
19 money. They are orphan drugs.

20 DR. LaFORCE: But they've been tested, they are
21 safe, and as far as we can tell they are effective, right?

22 COL. DINIEGA: Right. And they are used in the
23 special immunization program here, and also to protect laboratory
24 workers.

25 DR. SHOPE: Can't the military take it to FDA?

1 How did the Japanese encephalitis vaccine get taken?

2 COL. DINIEGA: Somebody in MPMC correct me because
3 I've been in and out from the MPMC, but Becon -- I think there
4 was an agreement with Becon that they would seek licensure in the
5 United States. If I'm not mistaken, the FDA goes over there to
6 inspect their plant, and they fall under the guidelines -- and
7 there has to be more data, and that's why we did more trials in
8 the U.S. Army and civilian --

9 DR. LaFORCE: Yes, because the approval was on the
10 basis of Col. Hoch's study, right?

11 COL. WITHERS: Right, we were interested because
12 of our operational needs, so it was a three-way deal that we
13 would do this testing.

14 COL. DINIEGA: And there was an indemnity clause
15 that was also part of the deal. But it is licensed for use.

16 DR. LaFORCE: Other questions? Yes, Bill?

17 DR. BERG: We seem to have identified two true --
18 what's the jargon here -- key performance parameters,
19 distinguishing between infection and vaccinee and then preventing
20 virus transmission, and when we say that we really mean
21 preventing infection, correct?

22 DR. LaFORCE: That's correct.

23 DR. BERG: One hundred percent? Ninety percent?
24 Because the phrase that's used in the ORD is "efficacy" and the
25 second key performance is "threshold 90, objective 95", and so

1 on. So, are we just going to leave that open, or are we going to
2 set a lower threshold, or are we just going to think about that
3 over dinner?

4 DR. LaFORCE: Is anybody a lawyer? This is a
5 great question for barristers, they can just sort of wordsmith
6 the words so that --

7 DR. BERG: My concern is if we say "combat and
8 prevent infection", somebody is going to go back and look and
9 say, "Let's see, what level -- oh, hey, we've got a threshold
10 parameter here", and we'll be stuck with something we said we
11 didn't want.

12 DR. LaFORCE: Well, what happens is it's the
13 difference about key versus nonkey, and if the issue is
14 preventing infection, that's fine, that's a key parameter because
15 that then becomes the gold standard by which you measure whether
16 this is going to be effective or not.

17 If you have as nonkey performance requirements, an
18 efficacy level of let's say 80 percent, it means that if it comes
19 in at 75 percent or, as somebody said, 78 percent, you're likely
20 to say that's okay, as long as it's not a key performance
21 requirement. I think it's probably a mistake, as I think most of
22 us think, to put a key performance requirement at 90 percent so
23 that if something comes in at 85 you're to wash this? That's
24 absurd.

25 DR. BERG: So what we're saying is any degree of

1 prevention is going to be accepted.

2 DR. LaFORCE: Right, except that somebody is going
3 to have to then sit down -- let's say it's 40 percent effective,
4 which is -- I mean, that's not so outlandish to think.

5 LtCOL. SCOTT: The study is not powered to detect
6 that. It's powered to detect --

7 DR. LaFORCE: Fifty percent, okay. Thank you.

8 LtCOL. SCOTT: The combat developer has already
9 unnominated that numeric requirement as key, just so you know.
10 We are no longer pursuing a key performance parameter with a
11 number 90 percent on it.

12 DR. LaFORCE: Thank you. You answered that
13 question.

14 DR. SHANAHAN: But as far as our opinion goes, I
15 think -- if it's not key, then there shouldn't be any reason of
16 making the statement at all because it is what it is. And it
17 basically become a motherhood statement. Yeah, you want it to be
18 as high as it can be, but if it's not an enforceable number, I'm
19 not sure we should even recommend any number other than --

20 LtCOL. SCOTT: They're all enforceable. They're
21 all enforceable, sir, but some are subject to what's officially
22 called the "trade space" in the DoD directive, without having a
23 level of oversight and review of the entire requirement. So,
24 once you've gone past the level of oversight and something is
25 designated key, there's a great burden of bureaucracy if you wish

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1 to redo it. There's a lesser burden if the combat developer and
2 materiel developer, the logistician, policy and science want to
3 work it out beneath that.

4 DR. SHANAHAN: And this is precisely why maybe we
5 should avoid putting any particular number on it.

6 DR. PATRICK: And you're only required to have one
7 key performance parameter in an ORD?

8 LtCOL. SCOTT: There must be a key performance
9 parameter, that's correct.

10 DR. LaFORCE: Distinguishing infection versus
11 vaccination.

12 COL. DINIEGA: FDA approval.

13 DR. LaFORCE: Oh, all right.

14 DR. ATKINS: But is there a problem with putting
15 the statement it should be effective without attaching a number
16 to it? I mean, implicitly we would be setting the threshold that
17 the study is powered for.

18 DR. LaFORCE: Fifty percent. So, you're going to
19 miss anything less than 50 percent.

20 DR. SHANAHAN: And whether you use it or not then
21 becomes an issue of efficacy balanced with economics and other
22 issues.

23 DR. LaFORCE: Balanced with how many doses that
24 has to be given.

25 DR. SHANAHAN: Right. I mean, there's a whole

1 logistics nightmare in terms of doing a vaccine, and if it's only
2 40 percent effective, you then have a real issue, but I'm not
3 sure it's our issue. See what I'm saying? I'm trying to get
4 away from us trying to dictate specific requirements in terms of
5 how the Army utilizes this thing rather than just -- basically,
6 what they are looking for is our support, which I think the
7 consensus is we generally can support it, but let's not hogtie
8 anybody.

9 COL. DINIEGA: I agree. If you don't have to be
10 specific, don't be specific because you're going to tie somebody
11 to a number or a figure or something.

12 DR. SHANAHAN: And I think there really -- in my
13 experience in MPMC and then research in general is that if you
14 have a failure, you really run a very severe risk of losing the
15 program all together. I mean, I don't think HIV is necessarily
16 going to go away completely, but it is a risk, you know, of
17 saying that, well, if you can't do it, we're going to give it to
18 somebody else, or just you get discouraged and go away or you
19 can't get the funding stream.

20 DR. ALEXANDER: At a minimum, it requires damage
21 control to maintain the steady-state, so if you can avoid that by
22 not putting those quantitative parameters in there, then you're
23 ahead of the game.

24 DR. SHANAHAN: And that's why I say we've got to
25 avoid putting third generation requirements on a first generation

1 drug or vaccine.

2 DR. LaFORCE: Okay. Other comments? Yes?

3 LtCOL. BERTE: In terms of the key performance
4 parameters, another scenario to think of -- and, Brian, correct
5 me if I'm wrong here -- but you have a key performance parameter,
6 and let's say you come up with a number -- and if we're talking
7 about percent efficacy, you say 80 percent and it comes in at 78
8 percent, but let's say it's conceivable that a manufacturer might
9 say, "This is good enough and I'm going to go off on my own at
10 this point because I feel like my risk is pretty much lower, and
11 I'm going to license it and go and produce it myself". At that
12 point, the military could turn around and say, "Well, we'll buy
13 it off the shelf when we need it". But if the key performance
14 parameter is in there for 80 percent, you can't even buy it off
15 the shelf. If you have an ORD, as I understand it, if there is
16 an ORD on the shelf --

17 LtCOL. SCOTT: You get yourself into a loop of
18 being forced to rescind an instrument, but that's not undoable.

19 LtCOL. BERTE: Well, I just threw that out because
20 that could happen.

21 LtCOL. SCOTT: If you write down a number and you
22 make it a key performance parameter and you don't reach that
23 number, you do have a great burden to undo that cooperative
24 agreement between the materiel developer, combat developer,
25 logistician.

1 LtCOL. BERTÉ: My argument is that you could make
2 an alternative path very difficult by making a key performance
3 parameter one of the numerical things, so you'd want to keep it
4 fuzzy. But if you do feel -- if the ORD requires that there be
5 some kind of way to measure efficacy, you're discussing possibly
6 going away from numbers, you may be -- they may want you to have
7 some kind of number in there to say, well, what do you mean, what
8 is efficacious? How do we know it's efficacious without a number
9 attached to it? One way to approach it might be to just broaden
10 that range. You can keep your objective up high, but just lower
11 your threshold to something that you're comfortable with, and
12 then as long as it comes in in that range, whether it's -- it may
13 come in at the threshold initiative and you can accept it, and
14 then as time goes on, if you give follow-ons, they can reach up
15 to that objective. So you don't necessarily need to lower your
16 threshold and objective, maybe if you have to have numbers, you
17 just need to lower the threshold to widen the range.

18 DR. CAMPBELL: The ORDs might be moot if the FDA
19 has their own standards for approving a drug, like if the FDA
20 requires it to be 80 percent effective, then it may not make any
21 difference what your ORD is.

22 DR. LaFORCE: But I don't think the -- the FDA
23 doesn't have a specific efficacy criterion. I mean, you can
24 license a vaccine that's 60 percent effective. In other words,
25 everything doesn't have to be 90 or 95 percent, although we've

1 gotten use to that.

2 DR. SHOPE: Look at Lime Disease.

3 DR. LaFORCE: Yes, look at Lime Disease.

4 COL. McNEIL: There's a prephase that we have with
5 the FDA, Col. Clayson talked about it, where we present the plan
6 to them. In that plan they will see we have a study designed to
7 detect at least 50 percent efficacy. They'll comment on that.
8 They don't care that much about efficacy, they care about safety.
9 They care about safety, safety, safety. And it's really up to
10 them just to say, okay, we believe that the trial you have
11 designed, the project you have designed is defensible, and if you
12 do that and then you come back to us seeking licensure, it ought
13 to be okay.

14 DR. LaFORCE: Well, listen, it's 4:30. I'm
15 starting to run out of gas, I don't know about the rest of you.
16 Bill.

17 DR. BERG: I assume we're going to make a draft of
18 some sort of statement on this tomorrow morning?

19 DR. LaFORCE: Yes.

20 DR. BERG: Would it be appropriate to at some
21 point have Col. Scott look it over to make sure we're not giving
22 him some language that gets in his way of what he wants?

23 DR. LaFORCE: What usually happens with this is --
24 and this you sort of have to trust me a little bit -- is we have
25 sort of a general agreement, and then we go back and forth, and

1 then cobble something together and, as President, if I have any
2 questions about whether this is going to be any different than
3 what we agreed to, I send everything out to you for you to look
4 at before it goes. But if it meets what I think was the general
5 consensus that we had and it's just a wordsmithing issue, we
6 usually -- Rick and I will take care of that.

7 COL. DINIEGA: Are you volunteering to write the
8 draft, Marc? You missed the first step where somebody usually
9 volunteers to write the draft.

10 DR. LaFORCE: We haven't gotten there yet. All
11 right. Other questions or issues? Yes, Ben?

12 COL. DINIEGA: On the issue of use, to just think
13 about how we used the hepatitis-B vaccine -- deployment to high-
14 risk areas, exposure to bodily fluids, and identified individuals
15 with high-risk behaviors. And in the case of hepatitis-B, it's
16 people who come into the clinics that usually get hepatitis-B
17 vaccinations.

18 DR. LaFORCE: In point of fact, I think what we're
19 coming to is a pretty reasonably defined higher risk stratum,
20 which really should be much more palatable than an overall
21 recommendation, although I must admit I would lean more towards
22 that, but given the realities that we've all presented, I think a
23 risk approach seems something that seems quite reasonable.

24 All right. Let me work on maybe an outline or
25 something like that.

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1 DR. HAYWOOD: Is it possible that that should be
2 two decisions, that is, a two-part decision about the objective
3 and the policy aspect and the other about the practical
4 application in terms of a first stage product?

5 DR. LaFORCE: Good point. I would think that if
6 everything goes well and there is a vaccine that appears -- let's
7 say the vaccine is 70 percent effective, that that's going to
8 precipitate an enormous discussion in terms of the preventive
9 Medicine Officers, in terms of what do you do with all this now,
10 and hopefully that will be an issue for discussion three years,
11 four years from now, at some AFEB meeting at sometime in the
12 future. That would be wonderful to contemplate that, that you
13 had an effective vaccine, and now you're talking about who do we
14 need to sort of work with to protect -- it's almost too good to
15 hope for.

16 DR. SHANAHAN: Marc, if I read the question right,
17 I think we've reached a consensus in terms of characteristics of
18 the vaccine, but it also asks use, which is a much thornier
19 question, and I'm not sure we do have a consensus on how to
20 address that particular point.

21 DR. LaFORCE: Let's go over the questions that are
22 there before we break up because there were actually a lot of
23 them, as I recall. Let's make sure that we're all on the same
24 page. I'm at 7, Tab 7, and it looks like the first -- this is
25 from the Deputy Surgeon, Subject: I request -- in other words,

1 the specific request is there. What level of effectiveness of an
2 HIV vaccine is acceptable for use by -- gee whiz.

3 DR. HERBOLD: We haven't discussed that one at
4 all.

5 DR. LaFORCE: That's right, we haven't discussed
6 that. What level of efficacy in protection from HIV infection is
7 acceptable?

8 Is a vaccine that prevents AIDS or other HIV-
9 caused disease acceptable for use in DoD personnel, if it does
10 not also prevent carriage and/or transmission of the virus? We
11 have discussed that.

12 How would use of the vaccine and other attended
13 preventive measures vary depending on the present/absence of
14 prevention of transmission?

15 How should DoD deal with the status of vaccinated
16 versus infected vis-a-vis deployability, assignment, and other
17 personnel actions?

18 Wow. I'm going to have to split this up, folks.
19 I can't do all of this.

20 Is inability to discern between being vaccinated
21 and being infected prior to onset of clinical illness an accepted
22 outcome of vaccine use? We've answered that question, and the
23 answer to that is "no". You must be able to distinguish.

24 In what subpopulations of DoD should an HIV
25 vaccine be considered for use? How does this vary with the

1 performance characteristics of the vaccine effectiveness,
2 sterilization, markers of immunity?

3 Who wants to volunteer for different parts of
4 this? (e) has already been answered. That's easy enough. I'll
5 write a sentence or two in terms of (e).

6 (a) and (b) appear to be somewhat linked. Do you
7 want me to try to sort of put something together in terms of (a)
8 and (b)? Okay. Who is going to do (c)?

9 (No response.)

10 I don't hear any volunteers.

11 DR. HERBOLD: I think this is a question of
12 preventing infection versus prevention of disease. And since it
13 is military policy to not deploy those who are infected, that
14 it's a treatment decision, I would say that -- and, John, you
15 need to correct me if I put the wrong words in here -- that the
16 DoD should not have their primary emphasis on the reduction of
17 the disease burden in infected military personnel.

18 DR. LaFORCE: You mean therapeutic vaccine versus
19 preventive vaccine? We're not talking about therapeutic
20 vaccines.

21 DR. HERBOLD: That's what the (c) question is, so
22 I'd say that would be on the bottom of my -- that should be on
23 the bottom of the list of things to do for the Department of
24 Defense.

25 DR. LaFORCE: Col. McNeil, is that okay?

1 COL. McNEIL: I don't think that's what the
2 question is saying.

3 DR. LaFORCE: Okay, help us out.

4 COL. McNEIL: The question is saying if you don't
5 prevent infection but you do prevent the occurrence of disease
6 events, if you slow the time to disease, or if you all together
7 prevent disease, is that appropriate? And the argument is that
8 would be great, but maybe that's not really what the DoD wants in
9 a vaccine. For us, really, preventing infection is more
10 important than preventing disease for the global population and
11 for public health in general. Preventing disease is wonderful,
12 especially because it probably comes with the inability to
13 transmit the virus. The reason that you don't have disease is
14 because the viral load has been regulated by the immune response,
15 and there's not secondary transmission either. That's inferred,
16 it's not proven, but that would be an effective vaccine, but
17 probably should not be the focus for DoD. A vaccine that induces
18 sterilizing immunity is more of a focus for DoD.

19 LtCOL. SCOTT: And if you answer the first
20 question, that infection is the focus, not disease, then you've
21 answered the question.

22 DR. ATKINS: It wouldn't prevent you from
23 including the CD foreign viral load as secondary endpoints, it's
24 just you wouldn't be able to make strong case based on that.

25 COL. McNEIL: It's really important to do that.

1 As a secondary endpoint, we would not be able to use that for
2 licensure. FDA doesn't look at secondary endpoints for licensure,
3 but the industry would love to see that and they would pursue it
4 with vigor and design a trial specifically to look at viral load
5 or disease occurrence. So, it needs to be in there because our
6 industry partners need that to be in there.

7 DR. LaFORCE: Bill, can you give --

8 DR. BERG: On (c)?

9 DR. LaFORCE: Yes, if you would.

10 DR. BERG: I'll give it a try.

11 DR. LaFORCE: Thank you. Who wants to take (d)?
12 That's pretty easy, that's just two or three sentences, and we've
13 talked about that. David, do you want to try that?

14 DR. ATKINS: Yes. I guess the -- I'm trying to
15 clarify what (d) is asking compared to (e).

16 DR. LaFORCE: Actually, let me do (d) and (e)
17 because it's really related to (e). So, I'll do (d) and (e).

18 DR. LANDRIGAN: It seems to me that if you can
19 discern between the two and if it's already DoD policy that the
20 person who acquires a wild infection doesn't go, then the answer
21 to (d) is obvious.

22 DR. LaFORCE: That's why I thought that was not
23 going to be too difficult to write.

24 LtCOL. RIDDLE: That one is actually being
25 discussed. I think they give some flexibility -- it was the Navy

1 that actually brought the issue to DoD asking for waivers now for
2 some individuals who are infected in critical specialty areas.
3 So, the current policy is being addressed right now. I included
4 the current DoD directive in your material, and I do have the
5 draft available to look at also.

6 DR. LaFORCE: Who wants to take (f),
7 subpopulations? We've already talked a bit about that. Would
8 you, Bob?

9 DR. SHOPE: Yes.

10 DR. LaFORCE: Well, then we've managed to
11 distribute that.

12 DR. SHOPE: You want me to just write something on
13 it?

14 DR. LaFORCE: Yes, if you would, please.

15 DR. SHOPE: For tomorrow morning?

16 DR. LaFORCE: Yes. And when I say write, if you
17 could write something this evening and then get it back to me
18 tomorrow morning -- it doesn't have to be fancy, just sort of
19 write it out, and we will go over that. And we may not get all
20 the periods, et cetera -- and I don't want to waste any time
21 wordsmithing -- but as long as we can get the general concept,
22 then we'll straighten it out.

23 Okay. That was very useful. Thank you, whoever
24 suggested going back to the actual questions themselves. That's
25 Ben, that's right.

1 COL. WITHERS: Just doing my job.

2 DR. LaFORCE: Thank you.

3 COL. WITHERS: It makes things easier, too, when
4 you just go back and look at the questions.

5 DR. LaFORCE: Any other questions or issues?

6 COL. DINIEGA: I'd like to sort of -- what time is
7 dinner?

8 DR. LaFORCE: Dinner? We're going to meet at 6:30
9 in the lobby.

10 LtCOL. RIDDLE: Reservations are under my name at
11 the restaurant at 7:00. Maps are in your books or on the back
12 table. We'll leave from the hotel at 6:30.

13 COL. DINIEGA: If you don't know where to go,
14 we'll caravan, and --

15 LtCOL. RIDDLE: You know where to go. And I
16 checked on the tour. This badge is okay for the tour. So, the
17 folks who want to tour will just --

18 COL. DINIEGA: They have to turn it in before they
19 go.

20 LtCOL. RIDDLE: Yeah, you've got to turn it in
21 before you leave.

22 DR. LaFORCE: I assume we can just leave our stuff
23 here?

24 LtCOL. RIDDLE: Yes, sir.

25 DR. LaFORCE: Any closing comments? Pierce

1 Gardner, nice seeing you?

2 DR. GARDNER: Thank you. Sounds like I missed a
3 great discussion.

4 DR. LaFORCE: Okay. Those of you who want to take
5 the tour, we've got to make sure that whoever is taking this tour
6 has got a car. Okay. Thank you, all.

7 (Whereupon, at 4:45 p.m., the meeting was
8 adjourned, to reconvene on Wednesday, May 23, 2001, in the same
9 room.)

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